



VOLUME

1

# APIC TEXT

OF INFECTION CONTROL AND EPIDEMIOLOGY

4TH EDITION





# TABLE OF CONTENTS

## VOLUME I

### Acknowledgements

Editors  
Authors  
Reviewers  
Production Staff

### Declarations of Conflicts of Interest

### Preface

## Section 1. Overview of Infection Prevention Programs

1. Infection Prevention and Control Programs
2. Competency and Certification of the Infection Preventionist
3. Education and Training
4. Accrediting and Regulatory Agencies
5. Infection Prevention and Behavioral Interventions
6. Healthcare Informatics and Information Technology
7. Product Evaluation
8. Legal Issues
9. Staffing

## Section 2. Epidemiology, Surveillance, Performance, and Patient Safety Measures

10. General Principles of Epidemiology
11. Surveillance
12. Outbreak Investigations
13. Use of Statistics in Infection Prevention
14. Process Control Charts
15. Risk-adjusted Comparisons
16. Quality Concepts
17. Performance Measures
18. Patient Safety
19. Qualitative Research Methods
20. Research Study Design

## Section 3. Microbiology and Risk Factors for Transmission

21. Risk Factors Facilitating Transmission of Infectious Agents
22. Microbial Pathogenicity and Host Response
23. The Immunocompromised Host
24. Microbiology Basics
25. Laboratory Testing and Diagnostics
26. Antimicrobials and Resistance

## Section 4. Basic Principles of Infection Prevention Practice

27. Hand Hygiene
28. Standard Precautions
29. Isolation Precautions (Transmission-based Precautions)
30. Aseptic Technique
31. Cleaning, Disinfection, and Sterilization
32. Reprocessing Single-use Devices

## VOLUME II

## Section 5. Prevention Measures for Healthcare-Associated Infections

33. Urinary Tract Infection
34. Intravascular Device Infections
35. Infections in Indwelling Medical Devices
36. Pneumonia
37. Surgical Site Infection

## Section 6. Infection Prevention for Specialty Care Populations

38. Burns
39. Dialysis
40. Geriatrics
41. Neonates
42. Pediatrics
43. Perinatal Care
44. Infection Prevention in Oncology and Other Immunocompromised Patients
45. Solid Organ Transplantation
46. Hematopoietic Stem Cell Transplantation
47. Nutrition and Immune Function

## Section 7. Infection Prevention for Practice Settings and Service-Specific Patient Care Areas

48. Ambulatory Care
49. Behavioral Health
50. Cardiac Catheterization and Electrophysiology
51. Correctional Facilities
52. Child Care Services
53. Dental Services
54. Emergency and Other Prehospital Medical Services
55. Endoscopy

56. Home Care
57. Hospice and Palliative Care
58. Imaging Services and Radiation Oncology
59. Intensive Care
60. Interventional Radiology
61. Long-term Care
62. Long-term Acute Care
63. Ophthalmology Services
64. Ambulatory Surgery Centers
65. Postmortem Care
66. Rehabilitation Services
67. Respiratory Care Services
68. Surgical Services

### Volume III

#### Section 8. Healthcare-Associated Pathogens and Diseases

69. Xenotransplantation
70. Biofilms
71. *Bordetella pertussis*
72. *Clostridium difficile* Infection and Pseudomembranous Colitis
73. Creutzfeldt-Jakob Disease and other Prion Diseases
74. Central Nervous System Infection
75. Enterobacteriaceae
76. Enterococci
77. Environmental Gram-negative Bacilli
78. Fungi
79. A. Diarrheal Diseases: Viral
- B. Diarrheal Diseases: Bacterial
- C. Diarrheal Diseases: Parasitic
80. Herpes Virus
81. HIV/AIDS
82. Influenza
83. Foodborne Illnesses
84. *Legionella pneumophila*
85. Lyme Disease (*Borrelia burgdorferi*)
86. Measles, Mumps, Rubella
87. *Neisseria meningitidis*
88. Parvovirus
89. Rabies
90. Respiratory Syncytial Virus
91. Sexually Transmitted Diseases
92. Skin and Soft Tissue Infections
93. Staphylococci
94. Streptococci

95. Tuberculosis and Other Mycobacteria
96. Viral Hemorrhagic Fevers
97. Viral Hepatitis
98. West Nile Virus
99. Parasites

#### Section 9. Infection Prevention for Occupational Health

100. Occupational Health
101. Occupational Exposure to Bloodborne Pathogens
102. Volunteers, Contract Workers, and Other Nonemployees Who Interact with Patients
103. Immunization of Healthcare Personnel
104. Pregnant Healthcare Personnel
105. Minimizing Exposure to Blood and Body Fluids

#### Section 10. Infection Prevention for Support Services and the Care Environment

106. Sterile Processing
107. Environmental Services
108. Laboratory Services
109. Nutrition Services
110. Pharmacy Services
111. Laundry, Patient Linens, Textiles, and Uniforms
112. Maintenance and Engineering
113. Waste Management
114. Heating, Ventilation, and Air Conditioning
115. Water Systems Issues and Prevention of Waterborne Infectious Diseases in Healthcare Facilities
116. Construction and Renovation

#### Section 11. Community-based Infection Prevention Practices

117. Public Health
118. Travel Health
119. Emergency Management
120. Infectious Disease Disasters: Bioterrorism, Emerging Infections, and Pandemics
121. Animal Research and Diagnostics
122. Animals Visiting Healthcare Facilities
123. Body Piercing, Tattoos, and Electrolysis

#### Index

# **VOLUME I**



# **Section 1**

## **Overview of Infection Prevention Programs**

## Infection Prevention and Control Programs

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### Abstract

*Infection prevention and control programs in the United States have changed significantly since the mid-20th century. Much of this change was a result of the influence of professional and nonprofit organizations; government, regulatory, and accrediting agencies; and scientific research and publications. Other influences include increasing acuity of patients, aging of the population, complexity and location of treatment interventions, and the increasing move toward care in home/ambulatory settings. There are various models outlined for infection prevention and control programs and standards developed for infection prevention professionals. This chapter includes information on Health and Human Services activities, the National Healthcare Safety Network, and information on international infection prevention and control programs.*

### Key Concepts

- Infection prevention and control programs have evolved significantly over the past 50 years.
- Infection prevention and control programs are affected by professional and nonprofit organizations; government, regulatory, and accrediting agencies; and scientific research and publications.
- An infection prevention team is an important component of the infection prevention and control program.

### Background

The first infection prevention and control efforts in the United States began in hospitals in the 1950s concurrent with the growth of intensive care and increasing staphylococcal infections.<sup>1</sup> Infection prevention and control programs extended into thousands of hospitals in the late 1960s and 1970s in

response to urging from various organizations (e.g., American Hospital Association [AHA] and The Joint Commission [TJC]).

In the decades since the 1970s, changes to these programs have occurred as a result of state and federal agencies, professional and nonprofit organizations, and scientific information published in journals. The 21st century brought increased attention to infection prevention and control programs because of government interest and oversight and activities of patient safety organizations. Other influences on programs include increasing acuity of patients, aging of the population, complexity and location of treatment interventions, and the increasing move toward care in home/ambulatory settings.

One major influence is the Department of Health and Human Services' road map for healthcare-associated infections (HAI) elimination outlined in 2008. It focused on broad programs to significantly reduce harm in hospitals and improve care across healthcare settings.<sup>2</sup> Elimination of HAIs requires a culture change for healthcare personnel (HCP) in which no infection is perceived as acceptable by any member of the healthcare team—support and direction from senior leadership is essential.<sup>3</sup> This support includes implementation of evidence-based practices, alignment of financial incentives, research, acquiring pertinent information, and accountability.

In addition, changes in the healthcare industry over the past few decades have placed increased demands on infection prevention and control programs. There are various quality improvement/patient safety activities focused on HAI reduction, including value-based purchasing, evidence-based practice centers, use of technology, implementing a culture of safety, and public reporting of data.<sup>4, 5, 6</sup> Public reporting, pay-for-performance, and reduced payment for hospital-acquired conditions have increased the focus on infection prevention.

While these changes were occurring, there have been dramatic successes in the infection prevention and control field resulting in decreased infections in hospitalized patients.<sup>7</sup> The modern concept of infection prevention and control also includes areas beyond HAIs (e.g., risk to employees, cleaning, maintenance and evaluation of the physical environment, health policy, and various other adverse events).<sup>8</sup> In addition, programs must also address risks to the public (e.g., emergency management, education of the community, and use of implementation science techniques).

Infection prevention professionals need to be alert to changing recommendations/requirements and new scientific literature and guidelines. They then need to make appropriate modifications to infection prevention and control programs. In addition, federal, local, and state requirements must be followed. This chapter outlines the specific agencies and organizations that have a major impact on infection prevention and control programs and the general issues to consider in the organization and function of infection prevention and control programs.

## Organizations Influencing Practice

### AMERICAN HOSPITAL ASSOCIATION

The AHA's Advisory Committee on Infections within Hospitals published its first edition of *Infection Control in the Hospital* in 1968. The purpose of this manual was to describe the elements of an infection prevention and control program that an AHA advisory committee "considers essential to the reduction and elimination of the human and economic wastage that results from our failure to prevent those



nosocomial infections that are preventable. . . ." Three editions of the manual were printed, the last published in 1979.<sup>9</sup> The AHA affected infection prevention and control practice through educational programs and conferences, journals and other publications, briefings, and consultants. Currently, the AHA issues Advisory Reports for healthcare executives, keeps track of legislative and regulatory issues regarding HAIs, and maintains its Hospitals in Pursuit of Excellence (HPOE) Web-based platform. The HPOE Website disseminates information, shares proven practices, and supports improvement activities. The HPOE has also developed Partnership for Patients Hospital Engagement Networks to disseminate best practices in 10 focus areas, including HAIs.

## ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

The Association for Professionals in Infection Control and Epidemiology (APIC) was established in 1972 to provide education and science-based information to strengthen and improve the practice of infection prevention. APIC's major influences on infection prevention and control activities are its development of professional and practice standards, education and training programs, a scientific journal, and governmental affairs activities. It established the Certification Board of Infection Control and Epidemiology (CBIC) in 1981 to administer an infection prevention and control certification program. APIC's research program was established in 1993 and is supervised by the APIC Research Committee. The committee coordinates initiatives focused on practical solutions, grounded in science, and that can be implemented across the spectrum of healthcare settings.<sup>8</sup>

APIC has partnered with other professional organizations to produce two consensus documents outlining infrastructure requirements for infection prevention and control programs in hospitals and nonhospital settings and a document defining practice and professional standards for the field.<sup>101112</sup> A competency model has also been developed for professionals to guide their acquisition of knowledge and skills over their career.<sup>13</sup>

## CENTERS FOR DISEASE CONTROL AND PREVENTION

In the 1960s, the Centers for Disease Control and Prevention (CDC) began recommending that hospitals conduct surveillance for the occurrence of healthcare-associated infections (HAIs; previously referred to as nosocomial infections). The CDC started training programs in infection surveillance in the early 1970s. The programs stressed surveillance for infections, developing and implementing policies for prevention of infections, and reducing wasteful activities (e.g., environmental culturing). Because of increased training opportunities available in the United States, the CDC discontinued these programs in 1983.

The Division of Healthcare Quality Promotion (DHQP) of the National Center for Emerging and Zoonotic Infectious Diseases is the CDC's focus for information, surveillance, investigation, prevention, and control of HAIs. The mission of DHQP is to protect patients, protect healthcare personnel, and promote safety, quality, and value in both national and international healthcare delivery systems.

In January 1970, the CDC began the National Nosocomial Infections Surveillance (NNIS) system. One purpose of this program was to monitor trends in HAI rates, pathogens, and antibiotic susceptibility patterns in the United States. The CDC transitioned NNIS to a Web-based knowledge system—the National Healthcare Safety Network (NHSN)—in 2005.

National surveillance of HAIs is coordinated and analyzed by NHSN; the program publishes HAI rate data. The NHSN data are intended for benchmarking and can be used by institutions in performance-improvement activities.<sup>14</sup>

State and federal requirements to report data to NHSN, creating a national database used by payers and various states, have led to changes in HAI reporting. These changes include a focus to change, improve, and validate surveillance definitions. Reliability of these data in an era of increasing public scrutiny is particularly important.<sup>15</sup> CDC has developed a method, known as the **Targeted Assessment for Prevention (TAP) strategy**, to assist facilities in using their own NHSN data to generate reports that help target infection prevention efforts to areas of greatest need.

In 1974, the CDC initiated a study to determine the efficacy of infection prevention and control activities in reducing the risks of HAIs in hospitals: the Study on the Efficacy of Nosocomial Infection Control (SENIC) project. The SENIC project defined an infection surveillance and control program as one containing three main elements:

1. Epidemiological surveillance for the occurrence of infections in patients within the hospital
2. Formulation of policies and procedures to control infections based on data generated by surveillance and other sources
3. Personnel specially trained in hospital epidemiology to collect the surveillance data and coordinate intervention activities.

The SENIC project compared HAI rates that occurred in 1970 and 1976 in a stratified random sample of U.S. hospitals.<sup>16</sup> The project found that compared to hospitals that had no program activities, hospitals that established infection surveillance and control programs reduced their HAI rates by approximately 32 percent.<sup>17</sup>

The DHQP began an HAI guidelines and recommendation process in 1981. Several documents were developed for specific infection prevention and control practices. This process was discontinued in the mid-1980s.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) was established in 1991 to provide advice and guidance to the CDC and others regarding the practice of infection prevention and control, and strategies for surveillance, prevention, and control of HAIs and antimicrobial resistance. The committee influences infection prevention and control programs through its periodic updating of guidelines and other policy statements. These guidelines are developed in partnership with various affiliated professional organizations.

## CENTERS FOR MEDICARE & MEDICAID SERVICES

As part of the Centers for Medicare & Medicaid Services (CMS) required conditions for certification and participation in Medicare and Medicaid programs, hospitals must comply with federal standards that include specific requirements for an active infection prevention and control program.<sup>18</sup> A program to investigate, control, and prevent infections in long-term care facilities accepting Medicare and Medicaid patients is also mandated by CMS.<sup>19</sup>

In addition, Conditions of Participation (CoP) apply to other healthcare organizations, including ambulatory surgery centers, home health agencies, hospices, some providers of outpatient services, and

psychiatric hospitals.<sup>20</sup>

The CoP related to hospital infection prevention was updated in 2013.<sup>18</sup> The standards include requirements to maintain a sanitary environment, designate an infection control officer, and develop, implement, and maintain an active infection prevention and control program.

CMS also updated its Medicare hospital inpatient prospective payment system in 2008. It no longer reimburses hospitals for certain hospital-acquired conditions (HAC) if it is high-cost, high-volume; not present on admission; would be assigned a higher payment because of the HAC; and could reasonably have been prevented through application of evidence-based guidelines.<sup>21</sup> These efforts are designed to increase health, improve care, and lower costs. There are concerns regarding use of administrative data versus standardized surveillance definitions as part of this process.<sup>22</sup> See Chapter 4, Accrediting and Regulatory Agencies, for more information on CMS requirements.

## CERTIFICATION BOARD OF INFECTION CONTROL AND EPIDEMIOLOGY

The CBIC is a multidisciplinary board that provides direction for and administers the certification process for professionals in infection control and applied epidemiology. CBIC is independent and separate from any other infection prevention–related organization or association. The mission of CBIC is to protect the public through the development, administration, and promotion of an accredited certification in infection prevention and control.

## FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) is responsible for implementing, monitoring, and enforcing standards for the safety, efficacy, and labeling of all drugs and biologicals for human use. Of particular interest to the infection prevention team are the FDA's activities related to food, blood, medical devices (especially single-use devices), and antimicrobial products and chemical germicides used with medical devices.<sup>1</sup> The Environmental Protection Agency also is involved in testing and use of hospital germicide products.

## HEALTH AND HUMAN SERVICES

The Department of Health and Human Services (HHS) is the principal agency for protecting the health of all Americans and providing essential human services. In 2009 the agency increased its focus on HAIs with the release of *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*.<sup>23</sup> The HHS has identified the reduction of HAIs as an Agency Priority Goal through its *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination*.<sup>2</sup>

## INSTITUTE FOR HEALTHCARE IMPROVEMENT

The Institute for Healthcare Improvement (IHI) is an independent not-for-profit organization helping to lead the improvement of healthcare throughout the world. IHI works to accelerate improvement by building the will for change, cultivating concepts for improving patient care, and helping healthcare systems put those ideas into action.

IHI's 5 Million Lives Campaign was a voluntary initiative to protect patients from 5 million incidents of medical harm over 2 years (December 2006 to December 2008). It included prevention of HAIs.<sup>24</sup>



IHI has targeted the identification and subsequent spread of best practices and established a focus on innovation regarding HAI reduction. Their current framework focuses on optimizing health system performance by centering on the health of a population, the experience of care for individuals within that population, and the per capita cost of providing that care.

## THE JOINT COMMISSION

The Joint Commission (TJC) started publishing minimal infection prevention and control standards for hospitals in 1953. In 1976, infection prevention and control programs became a specific requirement for accreditation by the TJC.<sup>1</sup>TJC's standards for infection prevention are used by many institutions, including hospitals, long-term care facilities, behavioral health facilities, and home health agencies, to establish a framework for an infection prevention and control program.

These standards have undergone many revisions over the years. In general, the standards state that the goal of the surveillance, prevention, and control of infection function is for the healthcare organization to identify and reduce the risks of infections in patients and HCP. There must be a functioning program, coordinating all activities related to the surveillance, prevention, and control of infections. The program should be doing the right things, doing these things well, be supported, and be focused toward improvement of processes and outcomes.<sup>25</sup>See **Chapter 4. Accrediting and**

**Regulatory Agencies**, for more information on TJC standards.

## NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

The National Institute for Occupational Safety and Health (NIOSH) was established in 1970 and became part of the CDC in 1973. It is responsible for conducting laboratory and epidemiological research on occupational hazards.<sup>26</sup>Decisions regarding types of devices used for employee protection (e.g., respirators, sharps containers) are part of NIOSH's mandate.

## OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Occupational Safety and Health Administration (OSHA) began its infection prevention and control activities in 1987 with the draft publication of bloodborne pathogens rules. These rules were finalized in 1991.<sup>27</sup>In 2001, a revision to the bloodborne pathogens rules was published to clarify issues related to sharps safety.<sup>28</sup>OSHA may enforce other infection prevention issues (e.g., tuberculosis) under the General Duty Clause of the Occupational Safety and Health Act. OSHA standards focus on determining employees' health risks as the result of exposure to communicable diseases.

## SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA (SHEA)

The Society for Healthcare Epidemiology of America (SHEA) was founded in 1980 to foster the development and application of the science of healthcare epidemiology.<sup>29</sup>SHEA's mission is to prevent and control HAIs and advance the field of healthcare epidemiology.

The organization provides educational programs, develops position papers, and produces a scientific journal. SHEA was a partner in the development of two consensus documents outlining infrastructure requirements for infection prevention and control programs.<sup>10,11</sup>

## Overall Structure and Function

Infrastructure documents outline the three principal goals for infection prevention and control programs:  
10,11

- Protect the patient.
- Protect HCP, visitors, and others in the healthcare environment.
- Accomplish the previous two goals in a cost-effective manner whenever possible.

Each institution is unique, and its specific needs must be considered when developing or reorganizing an infection prevention and control program. Factors include size, case mix, and types of care provided. The principal functions are generally similar, however, and include the following:

1. To obtain and manage critical data and information, including surveillance for infections
2. To develop and recommend policies and procedures
3. To intervene directly to prevent infections and interrupt the transmission of infectious diseases
4. To educate and train HCP, patients, and nonmedical caregivers

Because of differing needs, there may be various groups, individuals, and functions within the organization that are responsible for the infection prevention and control program. The following sections outline various persons and activities essential to an infection prevention and control program.

## INFECTION PREVENTION TEAM

Often the core of the infection prevention and control program is the infection preventionist (IP), chair of the infection prevention committee, and the healthcare epidemiologist. An individual responsible for occupational health or administration also may be a part of this team. The team is responsible for carrying out all aspects of the infection prevention and control program. There should be one person, however, who is designated as having responsibility for the program.<sup>10,11</sup> Team members must be qualified and guided by sound principles and current information. It should set goals, collect and analyze data, and select interventions.

A facility may have an infection prevention committee (IPC) that functions as the central decision-making and policy-making body for infection prevention. The IPC chair reports to the medical staff and/or administration. The IPC acts as the advocate for prevention and control of infections in the facility, formulates and monitors patient care policies, educates staff, and provides political support that empowers the team.<sup>30 31</sup>

The IPC must be multidisciplinary, composed of representatives from appropriate departments; examples include nursing, administration, engineering, pharmacy, building management. It should meet regularly, usually monthly or quarterly. Representation typically includes members of administration and clinical and ancillary staff. Because infection prevention issues and measures often cross departmental lines, an IPC that is multidisciplinary is crucial.

The IPC often refines and ratifies the ideas of the infection prevention team. Its members disseminate the information discussed in the meeting.

An IPC is not required by TJC; however, some states do require an IPC (also called an infection control committee). Institutions may support a committee structure for the reasons outlined earlier. If a committee is not used, the infection prevention team needs to develop other mechanisms (e.g., use of quality improvement [QI] models) to obtain multidisciplinary support for changes and actions. QI models use a collaborative approach, including use of multidisciplinary teams. These teams meet regularly and

are responsible for planning, policy development, interventions, and decision making. The team leader may be the infection prevention professional.

Dissemination of infection prevention information is a crucial component of an infection prevention and control program. Surveillance data and policy decisions should be communicated throughout the organization. This communication may be accomplished through routine written and/or verbal reports to clinicians, committees, and/or department heads and through various electronic methods. It is important to provide appropriate information to medical staff and administration as well as front-line HCP.

## INFECTION PREVENTION PROFESSIONALS

There are two key infection prevention professionals: the IP and the healthcare epidemiologist. The IP predominately has a background in nursing, medical technology, microbiology, or public health.<sup>32</sup>

Additional titles used by IPs may include *infection control nurse, infection control coordinator, nurse epidemiologist, infection control officer, and infection control practitioner*. The IP's role involves the daily collaborative efforts within all facets of healthcare. The IP typically functions as a consultant, educator, role model, researcher, and change agent. Infection prevention and control responsibilities include education, consultation, surveillance, implementation science, patient safety, and quality improvement.<sup>12</sup>

The healthcare epidemiologist may be the chair of the IPC or may occupy a separate position as either a technical advisor or member of the committee. This person is often a physician with special training in healthcare epidemiology and infection prevention. In the United States, the position is usually filled by an infectious diseases physician who works closely with the medical staff.

Depending on the institution, infection prevention professionals may report to administration, nursing or medical services, or quality improvement departments; other reporting relationships also exist. In some institutions, the infection prevention and control program is integrated with other departments (e.g., risk management, utilization/case management, patient safety, or quality improvement).

The role of infection prevention professionals includes responsibilities such as the following:<sup>10,11,12,31</sup>

1. Collection and analysis of infection data
2. Evaluation of products and procedures
3. Development and review of policies and procedures
4. Consultation on infection risk assessment, prevention, and control strategies (includes activities related to occupational health, construction, and emergency management)
5. Education efforts directed at interventions to reduce infection risks
6. Education of patients and families
7. Implementation of changes mandated by regulatory, accrediting, and licensing agencies (includes reporting communicable diseases to health departments)
8. Application of epidemiological principles, including activities directed at improving patient outcomes using implementation science<sup>33 34</sup>
9. Antimicrobial management
10. Participation in research projects
11. Provision of high-quality services in a cost-efficient manner

Some infection prevention professionals work less than full-time on infection prevention. They also may be involved in such areas as occupational health, quality improvement, patient safety, and risk management. In nonacute care facilities, infection prevention professionals typically have multiple roles



to fill and usually have a designated number of hours per week to devote to infection prevention activities.<sup>35</sup>

An infection prevention professional's time is split among data management, policy and procedure development, education, occupational health, quality improvement, program development, consulting, and investigating potential outbreaks. Infection prevention professionals should be involved in implementation science activities and some may take part in Institutional Review Board (IRB)–approved research activities.<sup>12</sup> Task and job analyses have been performed to specify what the infection prevention professional's day-to-day work may entail.<sup>36</sup> The development and availability of electronic data mining systems have impacted the infection prevention professional's day-to-day priorities, an area which is still under evaluation. The infection prevention professional may also be involved in investigations related to adverse outcomes other than infections.<sup>37</sup>

Successful infection prevention professionals improve their leadership strategies and pursue opportunities for self-development.<sup>6</sup> Certification for infection prevention professionals is available through CBIC. Practice and professional standards are available for various practice settings and professional backgrounds and include key indicators to be used in evaluating both the competency of the individual and their practice. The key indicators represent multiple skills considered necessary to meet the demands of the evolving healthcare environment.<sup>12</sup> In addition, competency models are available for professionals to use for successful practice.<sup>13,38</sup>

Many training courses exist for infection prevention professionals. Local and national APIC organizations, SHEA, state organizations, academic institutions, and private firms offer training courses. Courses are available for both beginning and experienced individuals.

## STAFFING

In 1969 the CDC recommended one full-time IP for every 250 occupied beds on the basis of pilot studies in eight community hospitals in which different staffing levels were evaluated.<sup>39</sup> The SENIC project strongly supported the 250-bed recommendation.<sup>16</sup>

Because the CDC recommendation is more than 40 years old, these staffing recommendations are outdated. This is especially true because there have been dramatically increased demands on the IP's time for surveillance, education, quality improvement, patient safety, and consultation in addition to many changes in healthcare. Changes in healthcare delivery have also expanded the range of infection prevention activities. These programs require sufficient resources to be effective and maintain program responsibilities.<sup>4,40,41</sup> In most acute care hospitals, the IP's scope of work is much greater than that evaluated in the CDC recommendation.

A 2004 Health Canada model projected three full-time IPs for every 500 beds in acute care hospitals.<sup>42</sup>

A group in the Netherlands estimated that one full-time IP was needed per 178 hospital beds or one per 5,000 admissions. The Dutch group also estimated one infectious disease physician was needed for every 25,000 admissions.<sup>43</sup>

One work group in California categorized the major functions of the infection prevention and control program created a method that uses workload units to develop staffing requirements.<sup>44</sup> A Belgian

Department of Health working group adopted a point system for staffing. The number of infection prevention professionals required is based on the number of points obtained by multiplying the number of beds of each patient-care unit by a factor that is specific for the patient population treated in the unit.

45

APIC initiated a Delphi project on staffing that was published in 2002.<sup>46</sup> It noted that staffing recommendations must consider the number of occupied beds, scope of the program, complexity of the healthcare facility, characteristics of the patient population, and unique needs of the facility. This study recommends a ratio of 0.8 to 1.0 IP for every 100 occupied acute care beds.

Long-term care facility resources have also been evaluated.<sup>47</sup> The Health Canada study estimated the need for one full-time IP per 150 to 250 beds.<sup>42</sup> The Delphi project assessed the need for 0.8 IPs for a facility with 100 beds, increasing to three for a 500-bed facility.<sup>46</sup> A Dutch group estimated a need of 500 hours per 100 residents per year.<sup>48</sup>

CMS does not specify either the number of infection prevention professionals to be designated or the number of hours that must be devoted to infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the program. It recommends using studies and recommendations on resource allocation published by APIC and SHEA to make staffing decisions.<sup>18</sup>

## Documenting Impact of Healthcare Associated Infections on Outcomes and Costs

The SENIC project found that one third of HAIs could be prevented by effective infection prevention and control programs that included surveillance and practice activities. The project also noted that prevention of approximately 6 percent of HAIs offset the cost of a program in a 250-bed hospital.<sup>16</sup>

Part of a program's effectiveness is a reflection of the influence of infection prevention professionals. They must be visible, provide a resource for staff, and use their scientific expertise when making specific recommendations. Effectiveness also depends on commitment to infection prevention by administration.<sup>49</sup>

It is important to outline the cost-benefit of an infection prevention and control program.<sup>50</sup> Demonstrating value is important for healthcare facilities that need to make economic decisions regarding support for infection prevention and control programs.<sup>51</sup> Targeted surveillance should be tied to specific interventions to decrease HAIs. Appropriate interventions to decrease infections will then result in documentation of cost savings.<sup>7</sup>

Economic evaluations can be used to compare costs with outcomes.<sup>52</sup> Cost-effectiveness and cost-benefit are examples of decision analysis studies. *Effectiveness* refers to the outcome of care. It can be expressed as the number of cases of disease prevented, the number of lives saved, or the number of life-years saved. *Cost-benefit* analysis looks at outcomes in terms of cost. Benefits other than direct financial costs also are important in evaluating the impact of infection prevention activities. These

include decreasing malpractice claims, protecting employees from injury, assisting in patient safety efforts, and enhancing the organization's image.<sup>53</sup>

Various methods can be used to estimate how much HAIs cost an institution. The cost of the infection prevention program itself consists of salaries, employee benefits, education, and commodity expenses. Cost-benefit estimates also can be developed for mortality and morbidity in patients. A crude estimate of cost can be obtained by multiplying the estimated numbers of HAIs at various sites by the site-specific cost weights (cost per infection) and adjusted for time. Other methods use actual cost weights or costs determined through prospective, randomized studies. Prevalence surveys also can be used to assess the costs of HAIs.<sup>54</sup>

## Influencing Practice

### CHARACTERISTICS OF THE ORGANIZATION

The ability of the infection prevention and control program to influence practices that affect safe patient care depends on certain characteristics of the patient population, patients' risk of infection, and characteristics of the organization and personnel. These characteristics include number of beds, professional school affiliation, geography, volume of patient encounters, patient population served, clinical focus, number of employees, and administrative philosophy. It is important to understand these characteristics when developing a program to optimally meet the infection prevention needs of the organization and the patients it serves.

Written infection prevention policies are often developed that relate to staff and patient-care practices, construction/renovation, emergency management, occupational health, and sterilization/disinfection. General policies are applicable to staff in the whole facility. These policies may form the basis of an infection prevention manual. Specific policies may also be developed for each unit or area. These policies must be supported scientifically and address the infection prevention needs for the institution.

However, providers of direct patient care must implement these policies consistently to benefit patients and protect staff. Infection prevention professionals usually attempt to affect patient care outcomes by influencing other healthcare personnel and their practices. Teaching personnel to increase their knowledge and skills of appropriate infection prevention practices is one method to influence quality patient care and protect employees. Education of staff is crucial to the success of any infection prevention and control program.

The infection prevention and control program thus influences practice through direct actions (e.g., review and evaluation of products, policy and procedure review and development, and observations). In addition, training and education of staff can assist in skill development and increase employees' knowledge base to affect practice.

### PATIENT SAFETY

Infection prevention personnel play a crucial role in preventing infections and other adverse events.<sup>55</sup>

Because of their expertise in epidemiological methods, IPs can support infection prevention, quality improvement, patient safety, and adverse health-event reduction programs. Infection prevention professionals can use basic healthcare epidemiology (e.g., surveillance, outbreak investigation, and special studies), implementation science, and other quality improvement tools (e.g., root cause analysis)

to improve patient outcomes. Implementation science can be useful in transitioning evidence-based practices into routine work.<sup>34</sup>

## ADMINISTRATIVE SUPPORT

It is important that the administrative leaders of the organization approve and support its infection prevention activities. Infection prevention professionals should schedule regular meetings with the administrator to whom they are responsible. This practice helps to maintain liaison between the program and administration and increase awareness of the institution's leaders of infection prevention and control program activities. There should also be routine reports presented to senior leaders.

## Quality of an Infection Prevention and Control Program

The interdisciplinary infection prevention team determines goals and objectives for the infection prevention and control program by performing an annual risk assessment.<sup>56</sup> These should be based on the institution's strategic goals and institutional data and findings from the previous year's activities. Identification of high volume, high risk, and problem prone activities is an important component of the risk assessment. Infection prevention resources and data systems needs should be evaluated in the context of these goals and objectives. The risk assessment can assist in setting priorities and obtaining support from key stakeholders.

Set priorities to help focus on appropriate allocation of infection prevention and control program resources. Realistic strategies for surveillance and intervention should be developed. Steps to use in this process include the following:<sup>57</sup>

1. Establishing a reliable, focused surveillance program based on the annual risk assessment
2. Streamlining data management activities
3. Analyzing HAI rates
4. Aiming for zero HAI rates
5. Educating staff regarding prevention strategies
6. Identifying opportunities for performance improvement
7. Taking a leadership role on performance improvement teams
8. Developing and implementing action plans that outline the steps needed to accomplish each objective
9. Evaluating the success of action plans in accomplishing the goals and objectives of the infection prevention plan

The quality of the infection prevention and control program should be assessed routinely by evaluating customer satisfaction, appropriateness, efficacy, timeliness, availability, effectiveness, and efficiency.

An annual evaluation of the infection prevention and control program is important to outline achievements and activities of the program and describe support requirements. The value of the infection prevention and control program to the organization should be emphasized, along with patient outcomes and cost savings. This evaluation report should be widely disseminated to leaders throughout the organization, in particular to the chief executive officer, chief medical and nursing executives, and board members.

An additional method to explain the importance of the program to others is through a mission statement, a description of the vision for the program, and an outline of core values.

## International Perspective

Infection prevention and control programs worldwide are organized around local guidelines and regulations to optimize quality healthcare and are influenced by various payer models;<sup>58</sup> there are many different models. The International Federation of Infection Control produces a handbook that includes information on infection prevention and control programs.<sup>59</sup> The World Health Organization recommends an appointed technical team of trained nursing and medical professionals who are responsible for organizing, implementing, and monitoring practices.<sup>60 61</sup>

Programs in most countries are coordinated through an infection prevention team, typically a physician (infectious disease physician) and an infection control nurse.<sup>62</sup> The infection control doctor could be a medical microbiologist, an epidemiologist, or an infectious diseases physician. An infection control nurse is typically a registered nurse with an academic education (perhaps with a qualification, such as specialized training) and practical training that enables him or her to act as a specialist advisor in all aspects relating to infection prevention and control.

The team coordinates the planning, implementation, and evaluation of the program. It is responsible for the day-to-day running of the program. Many programs use infection control link nurses to develop educational programs and provide operational support. They help identify problems, implement solutions, and maintain communications with the team.

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## Feedback form

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If you have questions or concerns about the contents of this chapter, please let us know. You can enter your comments for the editor in the form below or [text@apic.org](mailto:text@apic.org).

# Competency and Certification of Infection Preventionists

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## Abstract

*Professional development of the infection preventionist remains an essential component of practice. Increased focus on patient safety, as well as more intensive public reporting and regulatory requirements, places increasing emphasis on developing and maintaining the skills of the infection preventionist. Achieving competence can be accomplished by addressing the domains of the Association for Professionals in Infection Control and Epidemiology competency model and applying them to the infection preventionist's individual practice. The infection preventionist can begin the process by evaluating his or her current practice and using the tool to help determine areas for further*

*improvement, as well as career goals. A focus of the infection preventionist's development should include demonstration of competence through success in the certification examination, with recognition by earning the designation of being Certified in Infection Control.*

## Key Concepts

- Professional development is essential to keeping the infection preventionist up-to-date with the latest knowledge, skills, and strategies for preventing infections.
- Competence implies an expert level of knowledge and skill that is transferrable to the practice of infection prevention and control.
- Core competencies are necessary to ensure that the infection preventionist has a set of basic skills to integrate into any practice setting; these are defined by the Certification Board of Infection Control and Epidemiology, Inc.
- Certification is the pinnacle of practice and serves as one measure of validation of the infection preventionist's expertise.
- Advanced education is a mechanism to assist infection preventionists as they progress in their desired career paths.

## Background

Competence of the infection preventionist (IP) has traditionally been a mixture of subjective and objective interpretation, founded on an individual IP's position description. Competence is often assessed by comparison of the IP's current workload to the listed tasks on his or her performance evaluation. Recognized professional standards for the IP may or may not be integrated into such performance evaluations; if not, then this method of assessment lacks the objective criteria necessary to properly evaluate the IP with respect to his or her ability to apply skills and knowledge appropriately. The wide variability of assigned tasks associated with an IP's job can be daunting. Core competencies play a crucial role in guiding the IP to competence and to the next level of his or her career.

This chapter provides an introduction to the newly released Association for Professionals in Infection Control and Epidemiology (APIC) competency model, defines the various domains within the model and addresses the career levels of the IP, and discusses the significance of certification as a measure of practice validation.

## Basic Principles

What is competence? Competence in infection prevention and control, as in other specialty areas in healthcare, implies the ability to apply learned knowledge in a variety of different clinical settings and situations. Competence has been defined as the "essential knowledge, behaviors, and skills that an individual should possess and demonstrate to practice in a specific discipline."<sup>2</sup> Simply stated, it is the ability to put knowledge into action. Both theoretical knowledge and clinical experience are requisites for the competent IP, who must be able to readily adapt content and practical knowledge while making critical decisions on a regular basis.

While competence can be achieved through education and clinical experience, only certification of the IP formally recognizes competence and indicates that an individual has met the standards that are essential for the practice of infection prevention and control. Demonstration of competence is crucial for IPs as it serves as a tangible and public demonstration of professional and practice emphasis on protecting the safety of patients, healthcare personnel, and communities.

Certification is not the same as licensure, nor is it related to continuing education. It is, in fact, a step beyond both. Continuing education presents opportunities to acquire general or focused knowledge through lecture, discussion, or interactive methods. It may accompany some level of knowledge testing through a pre- and post-education assessment or demonstration, and plays a valuable role in introducing knowledge and areas of study. It does not, however, require specific knowledge or skill demonstrations that can be consistently measured or applied. Licensure indicates that an individual has met the minimum requirements to practice, whereas certification signifies that expertise has been attained in a specific field and that the certified individual has mastered the skills and knowledge required to practice competently in that field. In contrast to licensure, which is regulated by governmental organizations (e.g., state or provincial nursing or medical boards), certification is overseen by nongovernmental certifying bodies. Certifying bodies should, in turn, be accredited and meet accepted standards for the certification process. Certification provides the opportunity for the individual to demonstrate what has been learned through practice and continuing education by using standardized, validated methods to assess competence.

## The APIC Competency Model

The APIC competency model, initially introduced as a concept, identifies four separate but complementary and essential domains to describe areas of concentration for mastery by the IP.<sup>3</sup> These four domains encompass technology, performance management and implementation science, leadership, and infection prevention and control. The model also serves as a tool that enables the IP to assess his or her individual knowledge and skill and direct further professional development, and may be useful to identify future career paths. Central to the model is the safety of the patient; concentric layers reflect the advancing stages of the IP's professional career (career states), with the four domains intersecting every stage of the IP's career (Figure 2-1).

### CAREER STATES

The ever-changing landscape of healthcare requires the IP to develop and remain competent in the field. APIC has identified three levels of practice and outlined the competencies required in each level. There is no specific time frame identified for a person to advance through each level. Listed here, and shown in Figure 2-1, are some of the criteria needed to demonstrate competence in each level.

#### *EARLY (NOVICE)*

- Is completing or has obtained a baccalaureate degree
- Seeks information and develops fundamental infection prevention and control skills
- Performs surveillance and creates reports based on data
- Is learning the basics of epidemiology
- Develops policies



- Is preparing to become certified in infection prevention (Certified in Infection Control [CIC®]) through the Certification Board of Infection Control (CBIC)

### *MIDDLE (PROFICIENT)*

- Meets all of the requirements for the novice IP
- Has a baccalaureate degree
- Has achieved CIC®
- Has a diverse skill set
- Is a critical thinker
- Is considering work toward an advanced degree
- Mentors new IPs and those preparing for the certification exam
- Functions successfully in team-based activities
- Demonstrates competence as an IP and patient safety advocate
- Is active in a local chapter of a professional association or society
- Holds leadership positions at chapter level

### *ADVANCED (EXPERT)*

- Demonstrates competence at both the novice and proficient level
- Holds an advanced degree
- Demonstrates expertise in leadership, management, education, consultation, advanced analysis, and strategic planning
- Maintains and supports certification in infection prevention
- Mentors new IPs and those interested in becoming experts in the field
- Is a recognized leader and champion of patient safety and infection prevention
- Is involved in professional associations or societies at the chapter and national levels
- Presents educational programs at the chapter and national levels

**Figure 2-1.**

[View Image](#)



## THE DOMAINS OF THE APIC COMPETENCY MODEL

### *LEADERSHIP AND PROGRAM MANAGEMENT*

IPs' roles vary and may include specific leadership responsibilities. However, regardless of their official titles, IPs are considered subject matter experts and leaders in the field. The IP's leadership ability relies on the ability to influence others, using skills that facilitate prevention activities. Collaboration with leaders, other team members, and colleagues positions the IP at the forefront of the specific task or project, while placing emphasis on incorporating infection prevention in every department. Collaborative efforts of the IP may be manifested in the form of followership. The IP may not be leading the project or change effort, but the ability to demonstrate followership can be strategic and interdependent with leadership.<sup>4</sup>

## APIC Competency Model for the Infection Preventionist



White areas indicate critical competencies required for the expanding IP role.

\* The CBIC Credential is available from CBIC: The Certification Board of Infection Control and Epidemiology, Inc.

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The IP at any level must be able to manage the daily surveillance and regulatory workload and at the same time be prepared to address competing priorities that may arise. The IP does not have to be officially designated as the program manager to develop, maintain, and articulate the goals and objectives of the department. Each IP collectively contributes to the outcomes of the prevention efforts. Leadership builds effective programs and is evidenced by the ability to be flexible and realign goals when necessary. The IP includes in his or her arsenal critical-thinking skills to address complex situations and issues. One definition of critical thinking is "the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, and/or evaluating information gathered from, or generated by, observation, experience, reflection, reasoning, or communication, to guide belief or action."<sup>5</sup>

Competence in leadership may be most evident in the communication skills of the IP. The articulation of critical information must be timely, accurate, and address the various learning needs of the audience. Messaging of infection prevention information can

promote or inhibit, depending on how it is delivered.

### INFECTION PREVENTION AND CONTROL

Core competencies as defined by CBIC are identified by conducting periodic practice (job) analyses and are essential in developing the IP. Infection prevention is dynamic and continually evolving as emerging infectious diseases and naturally occurring events require new methodologies for prevention. Surveillance, including the application of definitions and analysis of data, is an area in which the IP must be knowledgeable. The IP uses surveillance data to identify trends and investigate outbreaks. The risk assessment, which identifies patient populations and potential organizationally inherent concerns that contribute to the development of healthcare-associated infections (HAIs), is a crucial program element. Performing a risk assessment adequately is essential in the development of prevention strategies to reduce risk to patients. Risk reduction includes not only the specific measures to reduce HAI rates, but also those related to construction and renovation, as well as the evaluation of new products and technologies.

Additional components of the infection prevention and control domain include antimicrobial stewardship (AS), education, and research. AS is defined as "the coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration."<sup>7</sup> The role of IPs in supporting AS programs is most evident by their role in surveillance for organisms of epidemiologic concern and their ability to share findings in a manner that promotes interprofessional practice and practice change. The IP supports the learning needs of the facility's employees as well as patients. Orientation and "on-the-spot" education are a few ways IPs deliver crucial information and train healthcare personnel in

prevention methods. The availability of the IP as an education resource highlights the significance of the role of subject matter expert. Education is often structured around the latest research and IPs should employ critical-thinking skills in the interpretation of the latest research; they may even participate in research studies if time and resources allow.

### *TECHNOLOGY*

HAI surveillance is an essential component of infection prevention practice that requires intensive, systematic collection, and analysis of data. As reporting demands increase at the facility, state, and national levels, IPs must be able to provide timely and accurate data to key stakeholders. IPs must be proficient in the use of surveillance technology and health informatics. Rapid changes in this domain will require mastery in the area of information technology (IT).

IPs are expected to have access to IT hardware and be proficient in the use of software including word processing, spreadsheets, and presentation and communications applications. In addition, IPs must also have ready access to clinical and administrative data related to patient care, such as electronic medical records (EMRs), admission/discharge/transfer (ADT) data and bed assignment information, and pharmacy, radiology, and surgery information. Often, IPs must engage IT professionals for assistance in extracting information from this myriad electronic resources. IPs must be skilled at communicating their needs to IT professionals and must be prepared to assist them in the development of requested reports. It is also important to validate automated reports to ensure accuracy and data integrity. In the United States, the advent of mandatory public reporting of HAIs and federal pay-for-performance initiatives that rely on infection prevention and control data make it crucial that IPs have solid support from their IT professionals.

As surveillance and reporting demands increase, more advanced analytical surveillance support tools have become essential. With interfaces from IT, source systems like EMRs, and ADT, pharmacy, radiology, and surgery databases, data mining systems can augment an infection prevention and control program by automating work that has traditionally been performed manually. Some surveillance technology systems can detect clusters and outbreaks, create automated alerts for multidrug-resistant organisms, and provide decision support to clinicians. All of these help improve the IP's efficiency by automating pieces of the surveillance process and aggregating data from many sources into one system. Many surveillance technology system vendors have collaborated with the Centers for Disease Control and Prevention (CDC) to support automated or semi-automated transfer of HAI data into National Healthcare Safety Network (NHSN) databases. As electronic methods become more commonplace and useful, it is incumbent upon IPs to be familiar with this technology. IPs should be able to make a business case for obtaining an electronic surveillance system, emphasizing the reallocation of their time from data collection and data entry to implementation of prevention strategies and interventions at the point of care. IPs must also understand both the strengths and the limitations of data mining and surveillance technology systems.

Relatively few U.S. health systems have a fully functional EMR that includes computerized provider order entry and clinical documentation. However, federally funded initiatives under The Health Information Technology for Economic and Clinical Health (HITECH) Act, also known as Meaningful Use initiatives, have incentivized the adoption of fully functional EMRs.<sup>8</sup> EMRs and electronic data warehouses can be powerful tools for collection and analysis of infection prevention and control data, including device days, impact of infections on resource utilization, and effectiveness of infection prevention and control interventions. IPs must have a knowledge base in IT systems as well as communication channels and relationships with their IT professionals to ensure inclusion in the development of electronic records and databases.

### *PERFORMANCE IMPROVEMENT AND IMPLEMENTATION SCIENCE*

Performance improvement and implementation science are complementary. In infection prevention and control, the goal of both is to improve quality of care by reducing HAIs through the consistent application of evidence-based practice and improved application of best practices at all levels and in all healthcare settings.

Implementation science refers to the process of translating evidence-based practices and research findings into practice.<sup>9</sup>It is the field of science that seeks to identify methods that facilitate and promote the integration of research findings and the evidence into healthcare practice and policy. The Institute of Medicine has embraced implementation science as a vital foundation for moving research findings into practice.<sup>10</sup>The notion of "translational research" looks for means to directly apply science into practice.

This concept is critical for the IP as it underscores the importance of research and finding answers to common, shared, and emerging questions in the field of infection prevention. The IP must have the skills to critically review and understand the scientific evidence regarding infection prevention interventions, and engage and educate a diverse group of stakeholders (e.g., nurses, radiology technicians, respiratory therapists, physicians, environmental services staff, administrators) to successfully implement those practices and research findings, and then to measure success and impact.<sup>11,12</sup>Integral to this process is the identification of facilitators of and development of strategies to

overcome barriers to implementation, in order to maximize acceptance of, and compliance with, the interventions by all relevant stakeholders. Examples of common barriers to implementation include lack of access to supplies, workflow and turnaround time constraints, and inadequate space or staffing.<sup>11</sup>

Tools such as bundles, checklists, daily rounds sheets, and automated reminders in EMRs help ensure that the practice is relevant and applicable to all patients and care providers. Measurable outcomes can be process measures and/or outcome measures.<sup>13</sup>Process measures refer to the practices of healthcare personnel in delivering care, such as compliance with equipment disinfection in between patients, hand hygiene, use of personal protective equipment, or adherence to a clinical bundle to prevent infection. Outcome measures refer to the results of care provided, such as infection rates, mortality rates, and readmission rates.

Performance improvement involves making changes to an existing practice or process in order to improve an associated outcome. An IP may be responsible for identifying specific areas of need and for leading performance improvement initiatives relevant to HAIs, developing a project charter, forming a team with clearly defined roles, selecting methods, engaging in rigorous measurement, and assuming accountability. Plan-do-study-act (PDSA) cycles, Lean Six Sigma, or continuous performance improvement (CPI) methods are all accepted methods for performance improvement activities. (See **16. Quality Concepts.**)

The importance of best practices cannot be overstated: Ultimately, patients deserve the finest care available. However, it is too often the case that evidence-based practices have not been adequately integrated. Implementation science and performance improvement are two essential disciplines that can allow IPs to foster a safe, efficient, and effective environment.

## Determining the Core Competencies Required for the Certified Infection Preventionist

In North America, certification in infection prevention and control is administered by CBIC ([www.cbic.org](http://www.cbic.org)), which was created by APIC in 1981 to develop and oversee certification for infection control professionals. However, CBIC is an autonomously functioning organization with its own volunteer board. At present there are almost 6,000 certified (CIC®) IPs, most of whom practice in the United States and Canada. The certification process used by CBIC is accredited every 5 years by the National Commission for Certifying Agencies (<http://www.credentialingexcellence.org/ncca>), whose mission is to "help ensure the health, welfare, and safety of the public through the accreditation of a variety of certification programs/organizations that assess professional competence." Additional information regarding certification excellence and the conceptual basis behind organized certification methods can be found on the Institute for Credentialing Excellence website (<http://www.credentialingexcellence.org>).

A job or practice analysis (survey) is conducted every 4 to 5 years to determine the competencies that a practicing IP should possess. This interval typically reflects the period over which major changes in most IPs' roles would become evident. The survey is distributed to certified IPs worldwide and members of partner organizations in North America (APIC and IPAC-Canada, formerly CHICA-Canada) in order to assess the knowledge and skills required of practicing IPs, as well as their current roles and responsibilities. Individual IPs may have varied roles and responsibilities and may need to employ different skill sets within their own workplaces, but the majority of these can be categorized into several major domains. A content outline, which identifies the major domains ("core competencies") of skills and knowledge required by practicing IPs, is developed based on survey responses. The content outline forms the basic framework around which examination questions for both the computer-based test (CBT) and self-achievement recertification examination (SARE) are constructed. The 2010 content outline was based on a practice analysis conducted in 2009.<sup>6</sup>

## Benefits and Impact of Certification

### BENEFITS OF CERTIFICATION

Certification is of particular importance in healthcare-related disciplines given the expanding scope of many specialties in an era when the complexity of both patient care and healthcare delivery is increasing. For infection prevention and control, there are the additional elements of intensified public and government interest in preventable HAIs.

Certification provides personal benefits to certificants: a sense of accomplishment and self-satisfaction; increased recognition, credibility, and confidence; and enhanced personal growth and development. Certification increases an individual's sense of empowerment compared with those who are not certified, as demonstrated in one study of critical care nurses. Certificants are also more likely to demonstrate a lifelong commitment to learning, enhance the profession, and are less likely to leave their current positions.<sup>14</sup>

### THE IMPACT OF CERTIFICATION

The most important benefits of certification in healthcare specialties are those that are provided to patients: improved clinical outcomes among patients who are cared for by certified staff. The association between certification and improved clinical outcomes is becoming more evident and has been demonstrated in intensive care and medical-surgical units, surgical services, and oncology.<sup>15,16,17</sup>

Certified staff may be better able to manage patient symptoms and are more knowledgeable regarding



established practice standards and guidelines.<sup>15</sup> Units with higher proportions of certified staff have had lower rates of falls and of urinary tract and bloodstream infections among critically ill patients.<sup>16,17</sup> In one study, 30-day inpatient mortality was inversely related to the proportion of certified staff within healthcare facilities.<sup>18</sup>

What evidence is there that certification in infection prevention and control similarly improves patient outcomes? To date, three published studies support the value of certification. Pogorzelska et al. highlighted the importance of certification among IPs and its significant impact on infection rates involving multidrug-resistant organisms, notably methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections.<sup>19</sup> In 2013, Saint and colleagues sought to determine perceived strength of evidence of common practices aimed at preventing device- and procedure-associated infections.<sup>20</sup> His team surveyed hospital IPs looking at practices implemented to prevent those types of infections, and results were stratified by certification status of IPs. Certified IPs were more likely to perceive the evidence as strong for certain preventive activities than were their noncertified colleagues. The implication is that certification may lead to greater use of evidence-based practice. Finally, Carrico and colleagues surveyed practicing IPs across multiple settings regarding immunization practices, vaccine handling, and program management.<sup>21</sup> Their findings indicated that programs managed by certified IPs were more likely to adhere to recognized best practices when compared with their noncertified colleagues. These three studies serve to recognize the value of IP certification and are the first to demonstrate that certification in infection control can positively impact practice and outcomes.

## The Certification Examination

### DEVELOPING AND SCORING THE CERTIFICATION EXAMINATION

Both the CBT and the SARE are computer-based examinations that consist of 150 multiple-choice questions. The 3-hour, proctored CBT is intended for the first time certifier and is geared toward the IP with 2 years' experience but is also available to those needing to recertify. The "open book" SARE, which may be completed while researching answers to questions, is intended to challenge the test taker to demonstrate continued mastery of infection prevention and control; it is only available for recertification and can be completed in multiple sessions on an ongoing basis over one calendar year.

As mentioned previously, the practice analysis forms the basis for both the CBT and SARE. Using responses from practicing IPs, content domains and measurable areas of knowledge and skill are identified and are used to develop the framework for the examination. Subject matter experts assist with development of new test questions (items) on a continual basis that are reviewed by those with expertise in psychometrics, a branch of science that deals with design, administration, and measurement of knowledge through test questions. Questions fall into one of three difficulty levels: recall questions which test the memorization or recall of specific information; application questions which require some interpretation of data or information provided; and analysis questions which may require problem solving or the assimilation of several pieces of information in order to derive the answer. Each question is then pretested through inclusion as an unscored (unmarked) item in current certification examinations. While candidates are made aware that 15 of the 150 questions on each exam are pretest items, they are not aware of the specific questions that are pretest items. After pretest items have been trialed, they are evaluated to determine their utility and reliability as part of the certification process. The evaluation relies on statistical and psychometric methods to determine whether pretest items are appropriate for



use in future examinations. Questions that fail to demonstrate value in the certification process are not included in future examinations. The interval between the development of a new question to its inclusion as a scored item on an examination spans several (6–12) months. All questions belong to CBIC and are copyrighted.

The certification examination itself undergoes continuous evaluation and improvement. Because changes such as updates to surveillance definitions or evidence-based recommendations occur frequently in the profession, questions are reviewed on a continual basis to ensure that they remain current. Outdated questions are discarded. If substantive changes are needed in order to update a question, the revised item is returned to the pretest question phase and reevaluated for inclusion in the examination. This process of continuous assessment and improvement demonstrates the attention and commitment to the certification process to ensure that it is a contemporary and valid assessment for competence.

Passing scores are determined based on the responses that are provided for each of the 135 scored questions. The method used to set the minimum passing score for both the CBT and SARE is the Angoff method, in which subject matter experts have determined how many correct answers are required for a competent candidate to successfully complete the examination. A candidate's ability to pass the examination depends on the knowledge and skill he or she displays, and not on the performance of other candidates. The actual passing score may change slightly for each version of the examination, to account for the slight variation in the difficulty of questions on each version of the examination. Historically, approximately 60 percent of first-time CBT test takers and over 95 percent of those taking the SARE are successful.

## PREPARING FOR THE EXAMINATION

Candidates should use the current content outline to guide them about domains of study and to develop a study plan. It is important to recognize that examination content is based on information obtained from the practice analysis and will assess all relevant domains of skill and knowledge that certified IPs require, even though all elements of the examination may not seem to be directly relevant to every individual taking the exam.

A number of different strategies have been employed by successful certificants. A list of references that are recommended for study is available on the CBIC website ([www.cbic.org](http://www.cbic.org)). The *APIC Study Guide* is a valuable resource for many candidates. Local study groups, which may be organized by APIC or IPAC-Canada chapters, may be helpful. Candidates may need to dedicate more study time to areas in which they have less experience or are less proficient, and may need to ask for guidance from local experts in these domains. Additional resources and educational offerings, available locally, through APIC or IPAC-Canada chapters or other professional societies, or from CBIC and APIC, may help to address areas of weakness or deficiency.

## APPLYING FOR AND TAKING THE EXAMINATION

First-time applicants must meet the eligibility criteria outlined by CBIC. Once certified, all certificants are automatically eligible for recertification at 5-year intervals. If certification expires, then individuals may only become certified again if eligibility criteria are met, as though applying for the examination for the first time; this may mean that a previously certified IP whose certification has expired and whose role has now changed may not be eligible to certify again. The CIC® designation may only be used by those whose certification with CBIC is currently valid.

Details regarding eligibility criteria, the application process, fees, and scheduling the examination are available in detail on the CBIC website ([www.cbic.org](http://www.cbic.org)).

## Conclusions

Competent practice is, and should be, the goal for all professionals. Approaching competence with a framework that identifies areas of expected practice outcomes, a roadmap for achievement, and a method for determining success are hallmarks of a well-designed process. Ensuring that infection prevention and control programs are led by competent professionals serves to protect the patient, family, caregivers, and healthcare personnel while actively demonstrating a commitment to high quality performance. This step also serves as a demonstration to the public that this group of well educated, expertly trained, and capable professionals is openly dedicated to ongoing improvement and validation of practice.

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## Feedback form

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## Education and Training

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### Abstract

*Few infection preventionists receive formal instruction in how to present intellectually exciting learning-centered activities, to lead engaging discussions, or to relate to adult learners in the healthcare environment in ways that promote motivation and independent learning. The learning environment in healthcare settings is unique because of the diversity of healthcare personnel. Diversity includes characteristics such as age, cultural background, ethnicity, education, and learning styles. Basic principles of adult learning have applied to the infection preventionist in the role of clinical educator with all types of healthcare personnel. These principles are applicable in a variety of clinical settings. Healthcare's complexity and rapid changes require that training activities also address issues of literacy, cultural diversity, cross-training, and technological advances. Successful educational activities in healthcare should be informed by learning theories and the educational needs of the learner population, the institution, and the community as they relate to infection prevention. Infection preventionists should provide an appropriate climate for learning as well as demonstrate creativity and flexibility.*

### Key Concepts

- The most basic goal of healthcare education and training is to improve job skills and competence.
- Workplace training in healthcare is a response to emerging issues in the field and tends to be problem-focused.
- Learning retention increases when immediate application follows instruction.
- Workplace education is business-driven and tied to administrative and financial goals, productivity, and the need to benchmark against the best professional practices.
- Needs assessments or performance improvement studies identify deficiencies in knowledge, skills, or attitude and serve as the basis for educational program development.

- An educator should develop a well-defined plan for each learning experience that includes goals, objectives, and appropriate teaching methods.
- Education and training should be linked to a facility's organizational vision, mission, and values.

## Background

Education and training today is more exciting and challenging than ever before. Now infection preventionists (IPs) facilitate learning for healthcare personnel (HCP) of all ages, from many different lifestyles, ethnic and cultural backgrounds, with different generational characteristics, and, most importantly, learning styles.<sup>1</sup> Education expertise is needed to assist HCP in the development of critical thinking skills to prepare them in the provision of the best and safest care for patients, visitors, other staff members, and for themselves. Educational philosophies have not been stagnant—they change as the larger social system matures—but they do provide foundations on which educational pedagogies are built.<sup>1</sup>

Learners are most successful when they are able to link new knowledge to the familiar. Providing education that addresses gaps in practice and complies with training that is mandated because of federal, state, or accreditation requirements poses significant challenges to HCP and the organization.<sup>1</sup>

With healthcare becoming one of the most heavily regulated of American industries, employees can anticipate an increase in institutionally mandated education. Healthcare facility administrators must ensure organizational compliance to minimize the threat of litigation or heavy fines for code violations. For the employer and employee alike, the business side of operations must be balanced with a clear understanding of organizational principles and values. Corporate compliance emphasizes that actions reflect the fabric of the organizational value system.<sup>1</sup>

Educators routinely use benchmarks to demonstrate the positive influence of educational interventions on worker performance.<sup>2</sup> Tracking performance outcomes and measuring effectiveness of training has become the norm.<sup>2</sup> Leaders recognize that to succeed in the new millennium, the goal for healthcare institutions is to develop employees to their highest level of performance while recognizing the diversity of the workforce. HCP are encouraged to acquire new knowledge and, in turn, share their expertise with others.<sup>1,2</sup>

Because of reengineering and reorganization, healthcare organizations are experiencing an increase in the growth of part-time and temporary staff, contract labor, students, and volunteers. Coupled with increasing average age, learner audiences will include a more diverse group with a wider array of worker expertise. This will require a new approach to engage the learner and will therefore require new teaching methods used by the educator. As part of performance improvement, HCP will assume more responsibility for workplace learning. Currently, performance appraisals in some facilities indicate the expectations for mastery of certain infection prevention skills.<sup>2,3</sup> With increased emphasis on facility report cards and public reporting of healthcare-associated infections (HAIs), the expectation is that more facilities will improve their compliance with infection prevention policies and procedures in employee appraisals.<sup>3</sup>

Effective workplace training initiatives will be directly linked to the implementation of professional and regulatory standards, as well as facility policies and procedures. IPs will develop training that is more



focused on skill development that is competency-based. Competencies describe worker skills, knowledge, and the mindset necessary to achieve effective job performance. These elements detail the specific outcomes or job expectations as indicated by role, work setting, and professional standards and facility-accepted benchmarks or best practices in the field. The focus is on the demonstration of individual competence by benchmarking rather than a comparison to fellow HCP or peers. For example, HCP may be required to demonstrate their abilities in sterilization, disinfection, and specimen handling, based on their job duties. The benchmarking process also ensures ongoing evaluation and monitoring.<sup>3</sup>

The impact of bioterrorism and new and unusual disease presentations, such as West Nile disease, monkeypox, severe acute respiratory syndrome, swine flu, Middle East respiratory syndrome, and avian flu, have increased the need for timely, thorough educational activities.<sup>4,5</sup> As new problems surface, new solutions will evolve and an educational program will be needed. To address these increasing demands, IPs must develop new strategies based on evidence-based practices to readily adapt to the learning needs of their audiences and their facilities. Similarly, with the recognition that adults learn in a variety of ways, IPs are expanding their teaching skills beyond the traditional lecture and slide show method. Incorporating technology in the educational change process is revolutionizing the way people are taught. Computer-based training can enable employees to manage time effectively and learn to be more independent and self-directed learners. An important goal is to assess and make recommendations for expanded and appropriate use of technology.<sup>2,3</sup>

## Basic Principles

### MAJOR GOALS IN TEACHING

IPs are in a unique position to have a direct impact on the facilitation of learning for HCP and staff. In the process of evaluation, IPs see their work in action, see the changes they affect and, in so doing, witness firsthand their goals and the goals of the institution coming to fruition. Learning outcomes for HCP should include increased competence in identifying problems, critical thinking, managing existing situations, and coping effectively with stress.<sup>6</sup>

The facilitation of learning can be by oral or written methods, and there are formal and informal methods. There are many factors the IP must take into consideration when addressing goals in teaching, such as: gender, cultural background, age, and the organizational culture. Other considerations in teaching goals are the accessibility of information, communication channels, clarity of message, flow control and information load, and methods to measure teaching effectiveness. The provision of opportunities for HCP to network with other personnel and share their expertise within the organization will expand the learner's creative abilities.<sup>7</sup>

### PRINCIPLES OF ADULT LEARNING

In order to plan and implement educational activities in healthcare, IPs need to know how adults learn best. Acknowledgment of the special needs of adult learners is also important. Finally, the six characteristics of adult learners must be taken into consideration for successful educational programs. Adult learners are autonomous and self-directed. They have a foundation of life experiences and knowledge and are goal oriented by nature. Adult learners are relevancy oriented and practical in healthcare settings. Adult learners need to be shown respect. For each characteristic, there are implications for you, the IP.<sup>4,5,6,7</sup>



Malcolm Knowles, a leader in the field of adult education, developed this framework describing how adults learn differently than children. His framework is summarized in Table 3-1.8

Educators must also be aware of and plan to confront common roadblocks to the learning process. One area that has been overlooked until recently is considering the specific needs of young adults in the workforce. This is an important concept because of the wide variation in ages of the adult learner. Young adult learners may need to be approached differently from an educational perspective from the more mature adult. Recognizing the differences in technological capabilities and how younger adults view their job responsibilities will require that teaching methods be adjusted as a means of engaging this group.

## BLOOM'S TAXONOMY

Bloom's taxonomy was created in 1956 under the leadership of educational psychologist Dr. Benjamin Bloom in order to promote higher forms of thinking in education, such as analyzing and evaluating, rather than just remembering facts (rote learning). This taxonomy of learning behaviors can be thought of as "the goals of the learning process." That is, after a learning episode, the learner should have acquired new skills, knowledge, and/or attitudes.9

**Table 3-1** Framework for Adult Education

Conditions of Adult Education	Principles of Teaching
The learners feel the need to learn.	<ul style="list-style-type: none"> <li>• The IP exposes the learners to new possibilities for self-fulfillment.</li> <li>• The IP helps the learners clarify their own aspirations for improved performance.</li> <li>• The IP helps the learners diagnose the gaps between their present level of performance and their desired level.</li> </ul>
The learning environment is characterized by physical comfort, mutual respect and trust, mutual helpfulness, freedom of expression, and acceptance of differences.	<ul style="list-style-type: none"> <li>• The IP provides physical conditions that are comfortable (as to seating, temperature, ventilation, lighting, decorations) and conducive to interaction (circle or small groups at tables).</li> <li>• The IP accepts the learners as persons of worth and respect their feelings and ideas.</li> <li>• The IP builds relationships of mutual trust and helpfulness with and among the learners by encouraging cooperative activities and refraining from inducing judgmental attitudes or competitiveness.</li> </ul>
The learners perceive the goals of the learning experience to be their goals.	<ul style="list-style-type: none"> <li>• The IP exposes their own feelings and contributes their resources in the spirit of mutual inquiry.</li> </ul>
The learners accept a share of the responsibility for planning and operating the learning experience.	<ul style="list-style-type: none"> <li>• The IP involves the learners in a mutual process of formulating learning objectives in which the needs of the learners, of the IP, of the institution, of the subject matter, and of society are taken into account.</li> <li>• The IP shapes their thinking about the options available in designing learning experiences and the selection of methods and materials and involve the learners in deciding among these options jointly.</li> </ul>

The learners participate actively in the learning process.	<ul style="list-style-type: none"> <li>The IP helps the learners organize themselves (teams, training projects, and so on) to share responsibility in the process of mutual inquiry.</li> <li>The IP helps the learners exploit their own experiences as resources for learning through such techniques as group discussion, case method, and projects.</li> </ul>
The learning process is related to and makes use of the experience of the learners.	<ul style="list-style-type: none"> <li>The IP gears the presentation of their own resources to the levels of experience of the learners.</li> <li>The IP helps the learners to apply new knowledge to their personal experiences and thus makes the learned material more relevant and integrated.</li> </ul>
The learners have a sense of progress toward their goals.	<ul style="list-style-type: none"> <li>The IP involves learners in developing mutually acceptable progress toward the learning objectives.</li> <li>The IP helps the learners develop and apply procedures for self-evaluation according to these criteria.</li> </ul>

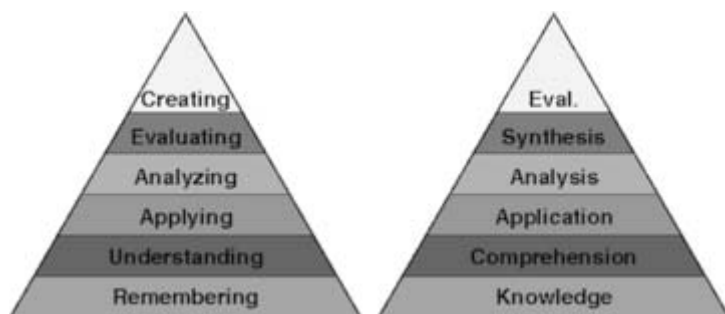
### THE THREE TYPES OF LEARNING

The committee identified three domains of educational activities or learning:<sup>9</sup>

1. **Cognitive:** mental skills (Knowledge)
2. **Affective:** growth in feelings or emotional areas (Attitude or Self)
3. **Psychomotor:** manual or physical skills (Skills)

This compilation divides the three domains into subdivisions, starting from the simplest behavior to the most complex. The divisions outlined are not absolutes and there are other systems or hierarchies that have been devised in the educational and training world. However, Bloom's taxonomy is easily understood.<sup>9</sup>

During the 1990s a new group of cognitive psychologists, led by Lorin Anderson (a former student of Bloom), updated the taxonomy to reflect relevance to 21st century work. Figure 3-1 shows the two graphics, the revised and original taxonomy. Note the change from nouns to verbs associated with each level.<sup>10</sup>



**Figure 3-1.**

Bloom's taxonomy.

[View Image](#)



**Table 3-2**

New Version	Old Version
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**Table 3-3**

Learning Behaviors	Goal of the Learning Process
<b>Remembering:</b> Can the learner recall or remember the information?	Define, duplicate, list, memorize, recall, repeat, reproduce state

<b>Understanding:</b> Can the learner explain ideas or concepts?	Classify, describe, discuss, explain, identify, locate, recognize, report, select, translate, paraphrase
<b>Applying:</b> Can the learner use the information in a new way?	Choose, demonstrate, dramatize, employ, illustrate, interpret, operate, schedule, sketch, solve, use, write
<b>Analyzing:</b> Can the learner distinguish between the different parts?	Appraise, compare, contrast, criticize, differentiate, discriminate, distinguish, examine, experiment, question, test
<b>Evaluating:</b> Can the learner justify a stand or decision?	Appraise, argue, defend, judge, select, support, value, evaluate
<b>Creating:</b> Can the learner create new product or point of view?	Assemble, construct, create, design, develop, formulate, write

## ACTIVE LEARNING

Often, as IPs prepare an educational session, they are thinking about what should happen in the session, and it is easy to go back to what we know and how we were taught—basically, the traditional pattern of "lectures and discussions." But to create significant learning, there are new tools and new kinds of teaching and learning activities. It is necessary to understand, and then learn, how to incorporate more active learning into our education and training programs.<sup>11</sup>

Active learning is one of the more powerful ideas to emerge in the literature on teaching and learning in the 1990s.<sup>11</sup>In essence, the concept of active learning supports research that shows: Learners learn more and retain their learning longer if they acquire it in an active rather than a passive manner. What do we mean by "active learning"? Active learning is described as involving the learners in doing things and thinking about the things they are doing. These "doing things" can be involving learners in activities such as debates, simulations, guided design, small group problem solving, case studies, and so forth. For example, when a learner is listening to a lecture or reading a textbook or work manual, they are receiving information and ideas—an important part of the learning process—but these also are relatively passive learning activities. To make learning more active, the overall learning experience needs to be enhanced by adding some kind of experiential learning and opportunities for reflective dialogue.<sup>11</sup>

Learning is not a spectator sport and the more actively engaged learners are, the more learning and retention takes place. Different instructional methods have greater rates of retention.

The pyramid in Figure 3-2 demonstrates the proportion of people who learn best from selected instructional methodologies. Most of us learn best when we're actively involved in the learning process (discussion groups, practice, teaching others).<sup>12</sup>

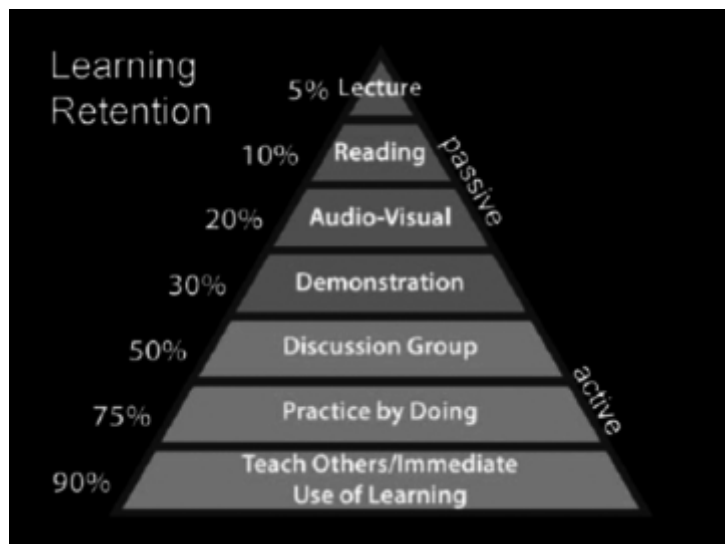
### Figure 3-2.

Learning retention: active learning versus passive learning.

[View Image](#)



*National Training Laboratories (Bethel, Maine)*<sup>12</sup>



There are several strategies to consider depending on your audience and the purpose of your training. Some of the strategies are particularly relevant for diverse audiences. For example, role-playing could be incorporated by having participants practice talking to a teacher, administrator, or someone else about noncompliance with hand washing that is occurring.<sup>11,13</sup> Other active learning strategies

include:

- Group problem-solving
- Case studies
- Simulation

- Quizzes
- Games
- Role-playing
- Brainstorming

### Side Bar:

An example of a simulation learning activity: Create a simulation of an event, such as a methicillin-resistant *Staphylococcus aureus* (MRSA) outbreak in the neonatal intensive care unit, and practice responding to it.

An example of the case study format: Have learners tackle *Clostridium difficile* scenarios taking into account Transmission-based Precautions, the environment of care, and exploring ways to promote optimal infection prevention activities.

The foundation of evidence-based education (EBE) is analogous to evidence-based practice (EBP) in the scientific literature. In order for an educational offering to be optimal, it is necessary to follow the principles of adult learning theory and active learning. One of the important points for IPs to keep in mind when preparing an educational program is the synthesis of evidence in an organized framework *that can be evaluated* in order to draw conclusions or to develop newer appropriate activities.<sup>14</sup> Societal directives insist on patient safety mandated through accrediting and governmental agencies with an ever-increasing emphasis on education and training.<sup>3,4</sup>

## EDUCATIONAL PROGRAM DEVELOPMENT

### PROGRAM CONTENT

Needs assessments or performance improvement studies identify deficiencies in knowledge, skills, or attitude and serve as the basis for educational program development. Assessing educational needs of the learner population, the institution, and the community, as it relates to infection prevention, is the first step in effective program planning.<sup>15</sup>

Improving learning transfer to workplace practices must be a high priority in the planning phase. Educators must link the previous knowledge and experience of participants to what is being taught,

using workplace situations to illustrate major points. The program content must be relevant, practical, and "doable" and should include practice sessions as a part of class activities. IPs should plan for reinforcement of knowledge in the work setting and ensure support from key leaders and supervisors.<sup>16</sup>

17

Fortunately, the infection prevention learning needs of HCP, the institution, and the community at large are interrelated. HCP participants need to know principles of infection control and prevention and current policies and procedures that govern infection prevention practice in their assigned areas of work. Facility administrators need to know how to develop institutional guidelines, policies, and procedures in accordance with accrediting and regulating groups. The citizenry or community populations need to know the factors that influence the development and spread of infectious disease.<sup>17</sup>

### *HEALTHCARE PERSONNEL COMPETENCE*

To be successful, it is important that HCP be able to transfer new knowledge into practice and be able to consistently apply this knowledge regardless of the setting. Work done by Gebbie and Merrill<sup>18,19</sup> defined a competency as a combination of knowledge, attitude, and skills. Hsu et al.<sup>4</sup> took this a step further and asserted that competency statements are broad and need to be aligned with specific statements of activity or performance that are measurable. Carrico et al.<sup>5</sup> applied this to infection prevention and provided the first set of competencies devoted to infection prevention among hospital-based HCP. The competency statements they propose include the following:

1. Describe the role of microorganisms in disease.
2. Describe how microorganisms are transmitted in healthcare settings.
3. Demonstrate Standard and Transmission-based Precautions for all patient contact in healthcare settings.
4. Describe occupational health practices that protect HCP from acquiring infection.
5. Describe occupational health practices that prevent HCP from transmitting infection to a patient.
6. Demonstrate ability to problem solve and apply knowledge to recognize, contain, and prevent infection transmission.
7. Describe the importance of healthcare preparedness for a natural or human-made infectious disease disaster.

The competency statements also contain specific measurable activities, or terminal objectives. These statements and activities may be used to provide the framework for HCP education across all disciplines. Further, this framework can be incorporated into the educational setting as part of the basic curriculum for the healthcare student. Competency-based education can be used as a basis for assessing training needs from a didactic approach and in support of classroom and hands-on learning approaches.

### *ASSESSING EDUCATIONAL NEEDS*

Performing a needs assessment will enable the educator to ensure the focus of an educational activity is relevant and reasonable for the target learner populations.<sup>15</sup> Study results will determine the interests of the group, readiness to learn, professional experience, and the cognitive differences in clinical reasoning.<sup>16</sup> Findings can be used to develop course goals and objectives and to assess the efficacy and impact of the educational activity.

Methods that can be used to determine educational needs of the learner population include the following:

- **Learner self-assessment:** The learner develops a self-achievement model and compares the present situation to the standard.
- **Focus group discussion:** Learning needs are assessed in small groups with members assisting each other to clarify needs.
- **Interest-finder surveys:** These are data-gathering tools, such as checklists or questionnaires.
- **Test development:** Tests can be used as diagnostic tools to identify areas of learning deficiencies.
- **Personal interviews:** The educator consults with random or selected individuals to determine learning needs.
- **Job analysis and performance reviews:** These methods provide specific, precise information about work and performance.
- **Observational studies:** Direct observation of personnel working can be performed by quality management analysts or IPs (e.g., hand-washing study in critical care units).
- **Review of internal reports:** Incident reports, occupational injury and illness reports, and performance improvement studies can be reviewed to determine specific learning needs of healthcare providers.<sup>16,</sup>

17

## GOALS AND OBJECTIVES

The educator controls the learning experience with a well-defined plan using goals, objectives, and appropriate teaching methods. Goals are statements that communicate the intent of the curriculum and provide a direction for planning the education session. Expectations are clearly defined in terms of time and available resources.

Once the purpose of the program is established, the educator determines the specific actions the learner will perform as a result of instruction. These actions are known as instructional objectives. There is no single, correct method or style for writing educational objectives, but there are general guidelines that should be followed. Properly written instructional objectives describe learner outcomes in measurable terms and use action verbs such as discuss, describe, demonstrate, compare, or evaluate.

Objectives describe each task or behavior the learner will be able to perform after completing the course, as well as the conditions under which each task or behavior will be performed. An educator includes objectives at various cognitive levels and with varying degrees of complexity. The most common model of increasingly more complex thinking is demonstrated by Bloom's taxonomy. The three lowest levels are: knowledge, comprehension, and application. The three highest levels are: analysis, synthesis, and evaluation. The taxonomy is a hierarchy with each level subsuming the ones below. In other words, a student functioning at the "application" level has also mastered the material at the "knowledge" and "comprehension" levels. These cognitive levels are shown in Figure 3-1.

## LEARNING ENVIRONMENT

One of the most important roles of the educator is to provide an atmosphere of mutual respect, one that is friendly, informal, and supportive. Eye contact, addressing students by name, listening without interrupting, and acknowledging the validity of problems or opinions expressed are characteristics of an effective teacher. Embarrassing the student or the use of intimidation or sarcasm is counterproductive to sharing information and resolving learning deficiencies.<sup>17,20</sup>



The educator must also take steps to create an environment that is comfortable and conducive to learning. The learning space should be private and congenial, with careful consideration to seating, room temperature, and lighting. The room should be properly arranged for learning transactions and should maximize physical and sensory potential.<sup>17</sup>As a courtesy, let participants know the location of restrooms and the timing of breaks.

The educator should eliminate distractions and try to control or decrease the noise level; ask that pagers and cell phones be turned to the inaudible range. The sounds of nonparticipants talking or laughing and sound of repairmen or custodial workers can be distracting to participants.

Provide audiovisual equipment that is in working order and ready for use. It is helpful to have a packet of information that describes the proper use and types of microphones, control switches, pointers, and any other technical devices in the room. Allow time for speakers to see the room and equipment before their presentation. Provide a designated person at the learning site to troubleshoot any facility or technical problems should they occur.<sup>18,19</sup>Test equipment before the learning session begins to ensure its functionality.

### *COMMON CLASSROOM SETTINGS*

The traditional classroom setup with straight rows of desks does not promote interaction. Better ways to arrange the classroom exist.<sup>21</sup>

The *horseshoe shape* is an all-purpose setup. It allows face-to-face participant contact and provides a writing surface. The educator and training equipment are positioned for easy visibility. Participants can be positioned inside the "U" for group activity.

*Team style* is achieved by arranging small tables and chairs around the room. It facilitates group activity and interaction. Some participants will have to turn their chairs around when the class reconvenes, but this is acceptable.

*Conference table style* is best if the arrangement is circular or square; if it is rectangular, it creates a "person's table" effect and a sense of formality. The facilitator is placed at the head of the table in the power position.

*Chevron or fishbone style*, a repeated V arrangement, creates less distance between participants and provides greater visibility of the educator. If the traditional classroom style is the only choice available, grouping the chairs in pairs promotes partnering. Provide enough space between rows to allow for the formation of quartets.

*Stadium or auditorium style* is a limiting environment for active training. Participants can be paired for brief activities requiring a learning partner, although it may seem awkward to participants.<sup>21</sup>

### *ENHANCING THE LEARNING EXPERIENCE*

An important factor for a successful program is having a well-regarded, experienced educator who facilitates the learning process by making course content understandable and memorable while engaging the participants. The learning experience should begin with an exercise that focuses on the learner and makes it personally relevant. The educator should define or redefine terms with respect to historical or current thinking and use examples or anecdotes to underscore major points. Major points should be emphasized with variations in voice intonation, speed, gestures, or overall body language.

Repetition should be used, repeating the same point in different ways. At the end of the learning session, summarize and review the major points.

The educator should engage the student in interaction with the material through activities such as dialogue, demonstration, role-play, and use of real-life examples. Audiovisual aids, such as slides, models, videos, posters, and whiteboards, are excellent support for the learning environment as well.

## USING LEARNING STYLE ASSESSMENTS TO FACILITATE LEARNING OUTCOMES

Knowing a learner's learning style will assist both the adult learner and IP to maximize the learner's learning experience. There are many learning style assessment tools that can be employed for the purpose of improving educator understanding of the mix of learning styles within the diverse HCP population. This information can then be used to determine the best teaching modalities to use with a particular group.

### *THREE COMMON LEARNING ASSESSMENT TOOLS*

1. The Kolb learning style inventory places the learner into one of four learning styles:
  - a. Accomodative—prefers concrete experience and active experimentation
  - b. Assimilative—prefers abstract conceptualization and reflective observation
  - c. Divergent—prefers concrete experience and reflective observation
  - d. Convergent—prefers abstract conceptualization and active experimentation<sup>22</sup>
2. The Dunn, Dunn, and Price Productivity Environmental Preference Survey (PEPS) is a self-diagnostic instrument and assesses four categories:
  - a. Environmental—preference for light, noise, emperature, etc.
  - b. Sociological—preference for studying alone or in groups
  - c. Physical—visual, auditory, or kinesthetic
  - d. Emotional—responsibility, persistence, and motivation<sup>23</sup>
3. The VARK inventory is an online assessment for auditory, visual, or kinesthetic preferences in learning.<sup>24</sup>The VARK can be found at the end of this chapter in the Supplemental Resources section.

Cognitive and learning style analyses have a special role in the process of personalizing instruction. Style elements are relatively persistent qualities in the behavior of individual learners. They reflect genetic coding, personality, development, motivation, and environmental adaptation. Second only to the more flexible teacher role, the assessment of learner learning style, more than any other element, establishes the foundation for a personalized approach to learning: for adaptive instructional strategies, and for the authentic evaluation of learning.

## TEACHING STYLES

Another variable that contributes to educator effectiveness in the clinical area is teaching style. Grasha's classification defines teaching styles as expert, formal authority, demonstrator, facilitator, and delegator.<sup>25</sup>The characteristics of each style are unique and are listed in Table 3-2.

Individual teaching styles involve behaviors and have a direct effect on the teaching-learning environment. The following are examples of behaviors and their effects on learners:

- Making eye contact encourages learners to participate in the session
- Positive facial expressions that elicit a positive learner response, such as head nodding, can assist learners in feeling comfortable dialoguing in class, whereas negative gestures, such as frowning, can discourage learner participation
- Vocal tone is very important and can easily portray underlying feelings and encourage or discourage learner participation

**Table 3-4** Teaching Styles Characterized by Grasha

Teaching Style	Characteristics
Expert	IPs use their vast knowledge base to inform learners and challenge them to be well prepared. This can be intimidating to the learner.
Formal Authority	This style puts the IP in control of the learner's knowledge acquisition. The IP is not concerned with learner-educator relationships, but rather focuses on the content to be delivered.
Demonstrator or Personal Model	The IP coaches, demonstrates, and encourages a more active learning style.
Facilitator	Learner-centered, active learning strategies are encouraged. The accountability for learning is placed on the learner.
Delegator	The IP role is that of a consultant and the learners are encouraged to direct the entire learning project.

Most educators rarely use just one teaching style. Most educators use a variety of styles, even within a single teaching-learning session. This mixed approach appeals to the variety of learning styles and has been shown to improve learning outcomes. Reflection on the type of style one uses most encourages self-understanding and may serve to improve teaching effectiveness.

## EVALUATION

Evaluation of educational programs is conducted to determine: (1) learner progress toward achieving program objectives; (2) effectiveness of the educational process to foster learner learning; and (3) accomplishment of the mission of the institution to prepare HCP for optimal infection prevention and control activities.

Program evaluation is necessary to measure change and growth in the learner.<sup>26</sup>Data collected from participants before, during, and/or after an education program is needed to demonstrate efficacy and impact. Feedback should be shared with learners, managers, and facilitators to demonstrate progress made and provide direction for further improvement. Specific program elements that should be evaluated include appropriateness of program design, adequacy of teaching and instructional resources, and the knowledge, skills, and attitudes learned by the participants. A representative sample of data from the learner population is necessary to provide evidence of successful learning.<sup>16,26</sup>

A decision on how evaluation results will be used should guide the development of instruments, questions, and protocols. A course manager can use this information to make decisions about what to improve, expand, or delete from future presentations. Findings can also be used by the organization to determine which types of programming work best and appeal to the learner, as well as measure response to innovative or controversial ideas. Evaluations also serve to provide program justification and accountability, often required by funding agencies, sponsors, or accrediting bodies.

## EVALUATION METHODS

The educator may use evaluation at different points within the program development process. *Formative evaluation* is conducted during the planning of the educational session to provide immediate feedback and to allow appropriate changes to be made. *Summative evaluation* occurs after the program is completed to determine impact and overall effectiveness.<sup>27</sup>

Various methods can be used to determine learning outcomes. Data collected by pretest and posttest before and after an intervention are used to measure change in individual or group understanding of the content. These tools help guide instruction by serving as a course outline. This type of evaluation design allows the educator to assess the appropriateness of the material presented for a particular audience and whether learning has occurred.<sup>27</sup>

Additional methods of evaluation include direct observation of practice, noting behavioral changes that are a result of the course (e.g., demonstration of proper use of protective barriers). Exit questionnaires are frequently used to gather information about the overall success of the program, asking for feedback on all aspects of the course, including objectives, presenter, quality of teaching aids, and the learning environment. One-on-one interviews may be used to collect more in-depth information from participants regarding understanding of concepts or preferences for program design.<sup>27</sup>

If a change in on-the-job behavior is anticipated as an outcome of the training exercise, the instructor should work with appropriate supervisors to determine whether the learning objectives were met. It may be necessary to review program content and learner reaction to this content with their supervisor. It is the supervisor's responsibility to advise the learner if job performance does not meet expectation. The educator may be involved in any additional coaching needed by the learner on the invitation of the specific supervisor.

Whatever evaluation methodology is used, the data must be gathered, tabulated, and analyzed to assess impact and make recommendations for curriculum revision before the next presentation. Evaluation measurements must be consistent with the objectives established for the educational program. Caution must be exercised when doing evaluations to prevent development of the Hawthorne effect, in which practice improves when the participant is aware that he or she is being observed. This underscores the importance of using unannounced and unobtrusive methods to monitor practices such as hand hygiene.<sup>27</sup>

## INNOVATIVE INSTRUCTIONAL METHODS

### POSITIVE DEVIANCE

Positive deviance is based on the observation that in every community there are certain individuals or groups whose uncommon behaviors and strategies enable them to find better solutions to problems than their peers, while having access to the same resources and facing similar or worse challenges.<sup>28</sup>

The positive deviance (PD) approach is an asset-based, problem-solving, and community-driven approach that enables the community to discover these successful behaviors and strategies and develop a plan of action to promote their adoption by all concerned.<sup>28</sup>

For example, in healthcare, PD bridges the gap between what HCP know and what they do. They know infection control protocols, but they may not follow them consistently. PD processes enable frontline staff

to identify practices that already work, and to discover for themselves the best ways to foster adherence at all times by all persons who come in contact with patients.

### *CREATING NETWORK MAPS*

Smart networks are described as networks that have a large core of overlapping clusters of individuals from different units in an organization, and a sizeable loose periphery of connections inside and outside the organization that bring in new ideas. The strategy of the PD MRSA prevention partnership is to use the social change process PD to enable frontline staff in different roles to work together across different disciplines and units to identify infection control practices that are already working.

Members of smart networks also collaborate to eliminate barriers to infection prevention, and to discover and implement ways to ensure that all persons who come in contact with patients adhere to all prevention control protocols at all times. To discover whether PD helped move a hospital system toward smart network structure, employees involved in the initiative went through a network mapping process. This included a survey that asked two types of questions.

The first set of questions, called attribute questions, measure characteristics of the survey takers—such as role, unit, and age. These provide different color options for the nodes or squares on the network map representing individuals. For example, on the maps shown in Figure 3-1, nodes represent the units and show how people tend to interact more with others in their own unit. The second set of questions, network questions, are used to track and measure the relationships among survey takers.

Survey participants were asked the following questions to develop five network maps:

- **Initial network:** With whom did you work on MRSA prevention before the PD MRSA initiative began? This is the beginning or baseline collaboration network.
- **Current network:** With whom have you worked on MRSA prevention since the initiative began? This shows changes in the collaboration network.
- **Innovation network:** From whom have you gotten new ideas or inspiration that helped your MRSA prevention efforts? This shows the degree and flow of innovation.
- **Project network:** List projects/activities and the people who are working on them. This shows how specific projects link people.
- **Potential network:** Who would you like to work with in the future on MRSA prevention? This helps organizations see helpful new relationships and plan for the future.
- **Social network analysis metrics:** The following metrics were developed by Valdis Krebs, a noted social network consultant and researcher, and colleague of June Holley. These metrics are used to measure network health.
  - **Awareness:** Who knows what is happening in the network, and how likely is it that information will spread? This measures whether the network is well-configured for information flow.
  - **Connector:** Who links people who would not otherwise be connected? How connected are different parts of the network? This measures the connectivity in the network.
  - **Integration:** Who are positioned to be network leaders, and what is the overall health of the network? This measures overall leadership and network health. Healthy networks have many participants, many lines of interaction and links among individuals and units, connections to expertise and resources across units, and some links outside the organization. They are not dependent on one-way communication from a few leaders.

*Holley J. Charting Pathways to Change: Mapping the Positive Deviance MRSA Prevention Networks at the VA Pittsburgh Healthcare System's Acute Care and Long-Term Care Facilities Shows Promise.* Washington, DC: Plexus Institute, 2007.

The selection of teaching style and instructional method depends on the resources of the institution and the preference of the educator. The educator understands and uses the basic principles of adult learning and has the ability to tailor the instructional method and teaching style to the specific type of learner population represented in the education setting (e.g., nonclinical employees, nursing assistants, resident physicians).

### *LECTURES*

Lecturing has been defined as "telling learners something they could not otherwise read in a book or review article." In this format, the speaker is able to cover a lot of material in a limited amount of time in both small and large groups. Learning theory tells us that lectures are not the optimal method for students to learn or retain new knowledge. The success of a lecture program depends on the relevance of the information to the learner and the presenter's public speaking ability. This type of program is enhanced when time is reserved for questions and answers or some other extended discussion between the speaker and participants.

More complex or voluminous materials can be presented in a symposium format, in which three to six lectures are presented in turn by content experts on various phases of a single subject or problem. This activity includes open discussion with the audience. Forum or panel formats can also be used. In a forum, one or more speakers engage in free and open discussion about the subject. A panel usually comprises four to seven presenters with special knowledge on the subject. Both of these styles of presentations can be combined to create an interesting program.

### *COMPUTER-BASED TRAINING*

A computer-based training module presents content in a logical sequence and guides the student to achieve specific learning objectives. This high-quality instruction combines the multidisciplinary expertise of the subject matter experts with innovative instructional design such as the use of video, audio, and other interactive formats to teach key concepts. Learner participation, immediate feedback, and colorful graphics are also attractive features that hold the student's attention.

Providing training via computers is versatile in that it can be used independently by individual learners or by groups in a classroom setting with an educator available to answer questions. This methodology provides a learning alternative for persons unable to attend scheduled classes.<sup>3</sup>

Lack of computer skills may be a drawback for some learners asked to complete computer-based training.<sup>3</sup> This method requires sufficient technical support because there may be installation and other capacity issues that come up. It may also be a challenge to ensure computer access for the target audience. It is reported that in many institutions, it's difficult for HCP to set aside the time needed to complete a module and there may also be a limited number of computer workstations available.

Using Web-based instruction to address infection prevention education and training can be of significant value. This learning opportunity provides access to materials for HCP whose workload demands are unpredictable and changing. It allows HCP to address their own educational and practice gaps at times that are most convenient for their work and home life schedules.



### *GAMES*

Well-structured games can facilitate learning and may be used as a "gathering tool" to introduce a concept or as a testing tool to assess learning. Examples of simple games are table-top quizzes during safety presentations and word search and word scramble puzzles.<sup>29</sup>

### *MASS TRAINING DELIVERY SYSTEMS*

For wide-scale institutional education, many facilities have worked with companies to personalize educational materials using an organizational intranet.

### *TRAIN-THE-TRAINER*

The train-the-trainer method may be an option for institutional education in situations in which large numbers of staff must be educated over a relatively short span of time. Leader guides are used to train those persons responsible for implementing the program and providing the ongoing staff in-service and continuing education. Leader guides are simply written and presented in a concise, systematic format, providing curriculum goals and objectives, course outline, instructional methods, references, and evaluation.

### *ROLE-PLAY OR REENACTMENT*

The dramatic teaching strategy of role-play or reenactment uses a situational learning experience and the technique of simulation to allow the learner to experience firsthand a professional dilemma as a spectator or as a participant. It can be used as a springboard for discussion in conjunction with a forum, panel, or symposium or as a building block for conferences and seminars with a focus on problem-solving methods. It also can be used in the development of an educational video.<sup>29</sup>

### *CASE STUDIES*

Case studies can be used as a training method to help bridge the learning gap between theory and actual practice. The method builds on a variety of learner skills: analytical, critical, and interactive. Learners explore multiple solutions and enhance creativity and problem-solving approaches often using a discussion-based format.

### *MENTORING PROGRAMS*

Mentoring is seen as a cost-effective way to upgrade and cross-train the workforce. In some organizations, there are formalized programs in which respected senior managers advise and groom promising candidates. Some employers encourage volunteer mentors from within the organization to assist with employee development and learning. Regardless of the program, mentoring is seen as a process in which the mentor and candidate work together to discover and develop the protégé's abilities.<sup>1, 3, 5</sup>

Mentors may be nominated, but, in general, the mentoring relationship is voluntary and remains active as long as it is beneficial. With correct preparation and managerial support, virtually anyone can become a mentor. Mentor and learner matching should be done by linking persons with assessed developmental needs with leaders in the organization having the needed expertise. Mentors and their charges may complete a self-assessment of leadership skills to identify areas of expertise and growth opportunities.

Mentors should be good listeners, focus on learner needs, be willing to share knowledge and expertise, and be capable of brutal honesty. Mentoring is practiced in partnership with an attitude of generosity,

openness, and trust, with both parties contributing freely.<sup>1, 3, 5</sup> The mentor may be at the same or a higher level than the learner, but is recognized as seasoned or experienced in the area or subject matter. The information revealed in the mentoring relationship is considered privileged and does not influence performance appraisals. Mentors teach, explore alternatives, inspire, act as a sounding board, build confidence and capability, facilitate learning, ask questions, listen with compassion, develop skills, create ownership, provide a challenge, act as a model, and explore potential. They provide the learner with tools, support, and structure to achieve more than what he or she might be able to do otherwise.

### *SIMULATION*

The use of simulation is deeply rooted in HCP training. Laboratories in which nurses learned the fundamental skills in patient care were often performed in a simulated setting where learning occurred before direct practice. In recent years, the use of simulation has advanced to the point of using human patient simulators as well as combining patient simulators with role players. The goal is to create a controlled learning environment that closely resembles the practice setting. This process facilitates use of practical and critical thinking skills on the part of the participant and serves to protect the safety of the patient.

One example relevant to infection prevention may be the creation of a mock isolation room. The goal may be to increase the awareness of the nursing staff regarding common infection prevention infractions that may occur during the provision of care. This would enable the participant to practice use of isolation precautions and personal protective equipment, as well as the infection prevention activities necessary to care for a patient with invasive devices such as intravenous lines, indwelling urinary catheters, feeding tubes, and mechanical ventilation. Environmental cleaning, preparation and provision of patient meals, performance of phlebotomy, and patient interaction are other examples of activities that can be honed and objectively evaluated in the simulated environment.

### *EDUCATIONAL CART*

Demonstration carts provide a portable means of displaying educational materials on a specific situation for diverse employee populations working various shifts. For example, the unit could be designed to display and store handouts from the Centers for Disease Control and Prevention (CDC) and various types of respiratory protection that are available for use. Other types of information available on the cart could include material on tuberculosis epidemiology and transmission, and skin testing protocol, along with diagnosis and treatment regimens, a patient teaching checklist, and an algorithm of infection prevention measures.

### *DVDs, CDs, AND VIDEOTAPES*

DVDs, CDs, and videotapes are useful formats for self-learning projects and can be obtained from most facility education and staff development departments, libraries, or resource rooms. Typically, these are inexpensive materials that can be easily transported and are user-friendly. Mobile units are helpful for on-site, "just-in-time" learning situations. Materials that are professionally produced and facility-specific may not be cost effective, depending on facility usage and how fast the information becomes outdated. It is wise to have several subject matter experts review a DVD, CD, or videotape before purchase to ensure the information presented reflects the infection prevention practices of the facility. Short video clips are helpful to demonstrate a point or to open the door for group discussion.

### *SELF-INSTRUCTIONAL MODULES*

Self-instructional modules are written to provide another alternative for the visual learner. They provide a self-paced approach to allow the learner to explore new information autonomously or in small groups. Modules should be user-friendly and simply written.

## Distance Learning

Interactive audio, graphic, and video conferencing systems allow for the exchange of information from one location to another through electronic communications. This innovative technology can also link healthcare providers in remote or underserved areas to specialty patient care services for fast medical consultation. It is also valuable in providing for ongoing employee education, training, and collaboration with other healthcare professionals.<sup>30</sup>

The overall effectiveness of the educational intervention depends on training and knowledge of equipment use. On-site communication experts or technologists should be available to provide speaker tips, "hands-on" instruction, and written materials for facilitating an effective presentation. If possible, observe distance learning in session and garner advice from experienced presenters.

Some points to remember when arranging a distance learning session are as follows:

- Determine the number of sites that will be "online" for your presentation.
- Know the number and location of necessary equipment such as cameras, monitors, microphones, or telephones. Practice using the equipment and test it before the start of the program.
- Introduce at least one spokesperson at each site. Try to call participants by name.
- Create a group comfort level and mutual regard for participants. Overcome the intimidation of electronic equipment by assisting each other.
- Engage participants in a balanced discussion. Involve on-site and off-site participants equally. Avoid side discussions.
- Ask a representative from each site to report transmission difficulties with sound or vision. If there will be a delay, it is best to announce it. If an off-site group must disengage for any reason, provide an explanation and continue with the presentation or discussion.
- Allow for breaks and questions. The speaker voice quality and the ability to pace and pause during the presentation are important skills to master for an effective delivery.
- Plan a debriefing session after the conference to assess program strengths and areas for improvement.
- Provide evaluations for off-site participants. Ask their assistance in providing feedback information to improve the quality of the program.

## Conclusions

Adults bring life experiences into the learning situation. Life changes can motivate adults to engage in new learning experiences. Learning new skills and knowledge takes time for integration to occur. Action plans, accountability, and follow-up all increase the likelihood that learning will take place. Theories of education are only a guide to the instructor. Effective instructors will be flexible, eclectic, and creative in the instructional presentations they make. Presentations must be perceived as interesting, useful, and relevant for the adult learner to willingly participate in the activity. Measurements of learning should be made over time to identify future training needs.

## Future Trends

In many situations, the learners who are novices in the domain of infection prevention and control are more expert in the uses of new communication technologies than their coworkers. So the workforce today in fact depends on a diverse set of participants, when the strengths of each are of benefit to the others. The increasing diversity of the workforce is predicted to become a strength; namely, as a source of innovation, rather than a barrier.

In the provision of healthcare there has been rapid change, and the IP's expertise is a double-edged sword. IPs must frequently reexamine their expertise, to be sure that it is still valid given the changes that have occurred. Often the specific facts and skills have a relative short "half-life." In these domains of rapid change, there is also power in naiveté—novices will suggest ways of thinking about the domain that may not have been useful previously, but may be useful given changes. Because those approaches were not useful previously, they may be automatically blocked out by experts. Again, with frameworks made available by new technologies, there are ways to involve learners in activity in the world outside of education in a way that is useful to the other participants in the activity.

Increasing demands for workplace education to address a complex and rapidly changing healthcare environment will require additional skills and resources for IPs. Reliance on outside sources of credible education will become more necessary as more unusual disease processes become evident. Collaboration with outside sources of education will also need to be enhanced. Nontraditional formats for education will have to be used to accommodate the changing needs for timely information on infection prevention practices and procedures.

## International Perspective

Concepts of transcultural care need to be incorporated into successful educational activities. Cultural backgrounds will affect the ability of the learner to participate in learning activities and accommodate new skills and ideas. Transcultural education will encompass different perceptions based on geography, gender, religion, social status, age, sexual orientation, and ethnic diversity. Care must be taken to minimize miscommunication when the instructor and the learners do not speak the same language. The development of a mentor relationship as a cultural quality control will help guide the instructor to develop appropriate educational activities.

## Supplemental Resources

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Positive Deviance Initiative (PD). What is positive deviance? PD website. 2014. Available at: <http://www.positivedeviance.org/>.

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## Accrediting and Regulatory Agencies

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### Abstract

*This chapter presents administrative issues for infection prevention and control programs and addresses historical and current pressures affecting accrediting and regulatory agencies at all levels that in turn, affect infection prevention and control programs. A brief description of the agencies, their relationships to each other, and their impact on infection prevention and control programs is provided, including a table with contact and website information for retrieval of more information.*

### Key Concepts

- The focus on patient safety, quality of care, risk reduction, and improving patient outcomes continues to develop in healthcare organizations across the United States. It includes all aspects of infection prevention and control programs with a broad scope that encompasses the program's integration with other departments in their healthcare organization, including nursing care, employee health, facilities maintenance and management, and quality improvement.
- Regulatory agencies, such as Centers for Medicare & Medicaid Services and accrediting agencies, such as The Joint Commission, encourage organizations to place more emphasis on infection prevention and control programs.
- Historically, the Agency for Healthcare Research and Quality was charged with developing a plan to reduce adverse patient outcomes and improve the safety of healthcare personnel and patients. The Agency, in collaboration with the Centers for Disease Control and Prevention's Division of Healthcare Quality Promotion, focuses on knowledge transfer (immediately usable information) and implementation of healthcare-associated infection prevention strategies.
- There has been increasing collaboration among federal agencies and new partnerships among federal agencies, private, and professional organizations to develop performance measures and to improve consumers' ability to compare healthcare delivery and patient outcomes.

- To function effectively, infection preventionists require a basic knowledge of the key agencies.
- Most agencies with an impact on infection prevention and control programs emanate from the executive branch, primarily within the Department of Health and Human Services and its major divisions of the Public Health Service: the Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health and the Agency for Toxic Substances and Disease Registry, the U.S. Food and Drug Administration, Health Resources and Service Administration, National Institutes of Health, Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services, formerly known as the Health Care Financing Administration. Other major agencies affecting infection prevention and control programs include the Department of Labor's Occupational Safety and Health Administration and the Environmental Protection Agency.

## Background

Extraordinary change occurring in the healthcare field has had a profound effect on current infection prevention and control programs. In the past, regulatory changes have driven related policy development of infection prevention and control programs (see **1. Infection Prevention and Control Programs**). Competitive forces have provided such an impact that even voluntary accrediting agencies have effected program changes in all care sites, including acute care, extended care, pre- and post-hospital care, inpatient rehabilitation, home care, and ambulatory care clinics. Examples of historical changes affecting infection prevention and control programs throughout the 1990s and the present include:

- The Joint Commission (TJC) standards published first in 1976 required hospitals seeking accreditation to have infection control programs; standards now place new emphasis on infection *prevention* and control. Another initiative TJC requires for accreditation, the National Patient Safety Goals (NPSG), escalated attention to healthcare-associated infections (HAIs) by including hand hygiene and reduction of device- and procedure-associated infections among current NPSGs and further expanded HAI issues in the 2009 standards.
- The evolution of the HIV/AIDS epidemic challenged healthcare to meet the medical needs of a growing number of very ill patients and to address occupational concerns and educational needs of all healthcare personnel. The emergence of HIV/AIDS as more "chronic disease" has had new impact, with a stepped-up emphasis on early HIV testing in the maternal and newborn population as well as in adults.
- SENIC: Publication of the results of the 10-year (1974–1983) Study on the Efficacy of Nosocomial Infection Control (SENIC) established the efficacy of hospital IPPs.<sup>1</sup>
- Development of the prospective payment system (PPS), a fixed payment hospital reimbursement system provided a financial motivation for hospitals to prevent costly infections in the late 1990s. An even greater impact occurred 10 years later that focused on HAIs: The Inpatient Prospective Payment System required limited payments for certain hospital-associated conditions, which included HAIs.
- Managed care systems and PPSs for long-term care continued exerting pressure on resizing systems throughout the 1990s. This included redesign of infection prevention and control programs for systems well beyond the borders of acute care settings. Ambulatory care systems are receiving new attention from the Department of Health and Human Services (HHS), both in Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), given the number of outbreaks of device-associated infections in nonacute settings.

- Threats from emerging pathogens and bioterrorism had a major impact on infection prevention and control programs beginning in October 2001, a month after the 9/11 attack on the Pentagon and World Trade Center. The era escalated with the dramatic event of *Bacillus anthracis* transmission through the U.S. postal system, continuing with current planning responses to potential biological agents, such as smallpox. Infection prevention and control programs played a major role in developing strategies for *Vaccinia* vaccination programs as part of the federal smallpox response plan. These major events, along with responding to new and emerging pathogens such as severe acute respiratory syndrome (SARS), added a major shift in priorities for programs already concerned with potential threats of an overdue influenza pandemic. HHS and the Department of Homeland Security have escalated plans for preparing for pandemic influenza under an all-hazards approach to natural and humanmade disasters. Infection prevention and control programs have seen a significant increase in their involvement and infection preventionist participation in emergency preparedness activities.
- Since the SENIC study, the single most important federal initiative to focus attention on the prevention of HAIs in healthcare facilities has been the 2009 publication of *The Department of Health and Human Services National Action Plan to Prevent Healthcare-Associated Infections*. The plan development involved all DHHS internal agencies and involved input from key stakeholders and public comment. The plan identifies key strategies for reducing HAIs, and sets proposed metrics and targets for acute care, ambulatory surgical hospitals, long-term acute care, and end-stage renal disease care facilities. This initially targeted reduction of HAI in acute care facilities, but the scope has expanded to include nonacute and ambulatory care settings. In response, all 50 states have released HAI reduction action plans.
- A major payment system change termed *value based purchasing* was established in 2010 under the Affordable Care Act. It provides incremental payments in a risk-adjusted approach, based on quality of care, implementation of evidence-based best clinical practices, and patients' experience of care.
- CMS requires public reporting of HAIs at the federal level, and at the state level in more than half of U.S. states. Reporting plans vary but generally focus on device-associated infections including central line-associated bloodstream infections (CLABSI) and Foley catheter-associated urinary tract infections, surgical site infections (SSIs), methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, and healthcare personnel influenza vaccination.

## Basic Principles

The impact of the Institute of Medicine's (IOM) reports beginning in 1999 has had a dramatic effect in healthcare, focusing on the importance of the healthcare environment's effect on patient outcomes.<sup>2</sup> The Agency for Healthcare Research and Quality (AHRQ) was charged with developing a plan to reduce adverse outcomes and improve the safety of personnel and patients. This focus on medical and patient safety continues to develop in healthcare organizations across the United States and includes all aspects of infection prevention and control programs. Given this emphasis on patient safety, accrediting agencies, such as TJC, encourage organizations to place increasing focus on infection prevention, as evident in the most recent infection prevention standards revision, including the 2005 CMS collaboration with the Association for Professionals in Infection Control and Epidemiology (APIC) in revising the Interpretive Guidelines (IG) for the infection prevention standards. One very visible result has been increasing collaboration among federal agencies, as well as increasing partnerships between the federal agencies and the private sector. These changes have a profound impact on infection prevention and control programs. For example, federal agencies concerned with quality or performance standards and

guidelines (e.g., CMS, AHRQ, CDC) are partnering with private and professional organizations, such as the American Hospital Association (AHA) and the National Quality Forum (NQF). The goal of the collaborative effort is development of similar performance measures in each care setting, improving the consumer's ability to compare healthcare delivery across similar care sites. One such initiative is the public reporting on several quality measures in hospitals, nursing homes, and home care, all of which include infection-related complications. As the focus on patient safety, improved outcomes, and transparency continues to expand and to function effectively, infection preventionists (IPs) require a basic knowledge of the key agencies and an understanding of their relationship to each other and to their specific program.

An enormous amount of activity occurred in terms of public reporting of HAIs since 2005. MRSA caught the attention of consumers and received intense media coverage; this was followed by similar attention to the problem of *Clostridium difficile* infection (CDI). The impact on the public was vast, with an increasing demand for accountability from healthcare on prevention and control of HAIs. Most states now mandate public reporting, congressional hearings and reports from the Government Accounting Office (GAO) have led to an intensified focus on HAI reduction or elimination at the federal level, and healthcare facilities are required to publicly report HAI outcomes and prevention practices, such as healthcare personnel influenza vaccination rates. This data is available and visible to the general public. Increased public awareness of HAI and infection prevention and control programs has led to increased visibility of infection preventionist and infection prevention and control programs and greater demand for accountability for patient outcomes. Never before has infection prevention been so highlighted or scrutinized so publicly.

## Accrediting and Regulatory Agencies

Against this backdrop of HAI awareness, the federal and state agencies remain a powerful influence, and their relationships within the government structure are described briefly here. A summary table of key selected agencies, committees, or programs (Table 4-1) accompanies the following explanatory remarks, provides a quick reference guide for easy access, and includes the current address for online resources available at the time of publication.

### GOVERNMENTAL AGENCIES AND ACTIVITIES

Governmental agencies can be placed organizationally in terms of their relationship to the three branches of the U.S. government. That is, agencies fit as extensions of the legislative, executive, or judicial branches of governmental structures.<sup>3</sup>The accompanying table highlights the fact that most agencies with an impact on infection prevention and control programs emanate from the *executive branch*, primarily within HHS; a key HHS agency is CMS, formerly known as the Health Care Financing Administration, although it is not designated as a member of the HHS's Public Health Service (PHS). Major divisions of HHS identified as members of the PHS include the CDC, especially the Division of Healthcare Quality Promotion (DHQP), the CDC's National Institute for Occupational Safety and Health (NIOSH), and the CDC's Division of Tuberculosis Elimination; and the Agency for Toxic Substances and Disease Registry (ATSDR). Other PHS agencies important to infection prevention and control programs include the U.S. Food and Drug Administration (FDA), Health Resources and Service Administration (HRSA), National Institutes of Health (NIH), and AHRQ. Other independent, key agencies of the executive branch or cabinet level departments include the Department of Labor's Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), the Department of Transportation (DOT), and the Department of Homeland Security.

The *legislative branch* had two agencies important to Congress for communication; today this is primarily the GAO because the Office of Technology Assessment has been closed and other resources provide those services.

**Table 4-1** Regulatory Compliance: Accreditation, Regulatory, and Professional Agencies and National and State Agencies With an Impact on Infection Prevention Programs

Major Department or Agency	Specific Agency	Programs or AHJ*	Telephone or Online Resource	F \
<b>Executive Branch</b> Health & Human Services: Public Health Service (PHS)	Centers for Disease Control and Prevention (CDC)	National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID)	<a href="http://www.cdc.gov/ncepid/">http://www.cdc.gov/ncepid/</a>	N C r S “ S
	Selections from Coordinating Center for Infectious Disease (CCID)			
	CDC	Division of Healthcare Quality Promotion (DHQP)	<a href="http://www.cdc.gov/ncidod/dhqp/index.html">http://www.cdc.gov/ncidod/dhqp/index.html</a>	N a
	CDC	DHQP		
	CDC	DHQP's Healthcare Infection Control Practices Advisory Committee (HICPAC)	<a href="http://www.cdc.gov/hicpac/index.html">http://www.cdc.gov/hicpac/index.html</a>	N a
	CDC	National Center for Immunization and Respiratory Diseases' Advisory Committee on Immunization Practices (NCIRD's ACIP)	<a href="http://www.cdc.gov/vaccines/pubs/ACIP-list.htm">http://www.cdc.gov/vaccines/pubs/ACIP-list.htm</a>	N a

CDC	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)	<a href="http://www.cdc.gov/tb/default.htm">www.cdc.gov/tb/default.htm</a> <a href="http://www.cdc.gov/maso/FACM/facmACET.htm">http://www.cdc.gov/maso/FACM/facmACET.htm</a>	N a
CDC	National Institute for Occupational Safety and Health (NIOSH)	<a href="http://www.cdc.gov/niosh/about.html">http://www.cdc.gov/niosh/about.html</a>	N t
CDC	Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)	<a href="http://www.bt.cdc.gov">http://www.bt.cdc.gov</a>	N a
CDC ATSDR  Distinct from but overseen by the CDC	Agency for Toxic Substances and Disease Registry (ATSDR)	<a href="http://www.atsdr.cdc.gov">http://www.atsdr.cdc.gov</a>	N C t h s e f
Food and Drug Administration (FDA)	FDA  Safe Medical Device Act (SMDA)  Safe blood supply (both the FDA and CDC)  Food safety for all but meat, poultry, and eggs  Vaccine Adverse Event Reporting System (VAERS)	<a href="http://www.fda.gov">http://www.fda.gov</a>	F E ( a c c s c t a P L



	Health Resources and Services Administration (HRSA)	HRSA Health Delivery Services	<a href="http://www.hrsa.gov">http://www.hrsa.gov</a>	F N F t C t a
	Agency for Healthcare Research and Quality (AHRQ)	AHRQ guidelines	<a href="http://www.ahrq.gov">http://www.ahrq.gov</a>	N C h r a
	National Institutes of Health (NIH)	NIH Improve health of nation 14 research institutes; National Library of Medicine (NLM)	<a href="http://www.nih.gov/">http://www.nih.gov/</a> <a href="http://www.nlm.nih.gov/">http://www.nlm.nih.gov/</a>	N N
Health and Human Services <sup>a</sup>	Centers for Medicare and Medicaid Services (CMS)	CMS Oversight for Medicare/Medicaid Participation conditions Payment system	<a href="http://www.cms.gov">http://www.cms.gov</a> (access for Medicare databases for long-term care, home care) <a href="http://www.cms.hhs.gov/HospitalAcqCond/01_Overview.asp">http://www.cms.hhs.gov/HospitalAcqCond/01_Overview.asp</a> (Hospital-associated conditions [HAI])	F F C ( C  C F c F
Environmental Protection Agency (EPA)	Independent agency	Regulated medical waste Resource Conservation and Recovery Act (RCRA) Medical waste Disinfectants for hard surfaces Antimicrobial pesticides	<a href="http://www.epa.gov">http://www.epa.gov</a> <a href="http://www.epa.gov/osw/nonhaz/industrial/medical/mwfags.htm">http://www.epa.gov/osw/nonhaz/industrial/medical/mwfags.htm</a> <a href="http://www.epa.gov/oppad001/dis_tss_docs/dis-01.htm">http://www.epa.gov/oppad001/dis_tss_docs/dis-01.htm</a> <a href="http://www.epa.gov/oppad001/regpolicy.htm">http://www.epa.gov/oppad001/regpolicy.htm</a> Antimicrobial hotline: 1-703-308-0127	F C I F a n t s a a t I F F (

Department of Labor (DOL)	Occupational Health and Safety Administration (OSHA)	OSHA standards	<a href="http://www.osha.gov">http://www.osha.gov</a>	F
	DOL-OSHA	General safety and health standards	<a href="http://www.osha.gov/SLTC/bloodborne pathogens/index.html">http://www.osha.gov/SLTC/bloodborne pathogens/index.html</a>	E f e c g
	DOL-OSHA	OSHA's standards	<a href="https://www.osha.gov/SLTC/tuberculosis/">https://www.osha.gov/SLTC/tuberculosis/</a>	F
		Respiratory protection: Std 1910.134		M t c
		General Industry Respiratory Protection Standard (GIRPS)		C n a r a
Department of Transportation (DOT)	Independent agency DOT	Research and Special Programs Administration (RSPA)	<a href="http://www.dot.gov">http://www.dot.gov</a>	F  F h n c
Department of Agriculture (USDA)	Independent agency USDA	Food Safety Inspection Service (FSIS)	<a href="http://www.fsis.usda.gov/">http://www.fsis.usda.gov/</a>	F  F f f
Department of Homeland Security (DHS)	Independent agency DHS	Emergency preparedness and response (DHS)	<a href="http://www.dhs.gov/index.shtm">http://www.dhs.gov/index.shtm</a>	F
<b>Legislative Branch</b>	Congress: Government Accounting Office (GAO)	GAO provides Congress with information on public spending	<a href="http://www.gao.gov">http://www.gao.gov</a>	N
Congress			Search on Infections	I
Congressional Information Agency	Expenditures: GAO			

<b>Voluntary Accreditation</b>  The Joint Commission (TJC)  American Osteopathic Association (AOA)  Det Norske Veritas Healthcare Inc. (DNV)	Nongovernmental accreditation: TJC, AOA, DNV	TJC: outgrowth of AHA, ACS, AMA, ADA, ACP  AOA  DNV	<a href="http://www.jointcommission.org/">http://www.jointcommission.org/</a>  <a href="http://www.osteopathic.org/">http://www.osteopathic.org/</a>  <a href="http://www.dnv.us">http://www.dnv.us</a>	V  N  F  S  M  ii  a
	National Committee on Quality Assurance (NCQA)	Nongovernmental accreditation  Other: HMO  NCQA: Accredits HMO and outpatient settings	NCQA: collaboration as of 1998 with JCAHO and AMAP for quality council/measurement  <a href="http://www.ncqa.org">http://www.ncqa.org</a>	V  F  r  a  F  F  g  f
	Laboratory  College of American Pathologists (CAP)  Commission on Office Lab Accreditation (COLA)	CAP  COLA	CAP and COLA: certify laboratories that TJC recognizes as “deemed status”  <a href="http://www.cap.org">http://www.cap.org</a>  <a href="http://www.colab.org">http://www.colab.org</a>	V  S  li
	<b>States</b>  Department(s) of public or community health	Disease control; laboratory services  Infectious disease control services of some type	URL is state specific	F  C  A  M  S  G
	Agencies charged with health care facility enforcement	Enforcement of CoP with Medicare/Medicaid; OBRA and ECF; construction codes; office of fire safety; enforce CLIA	Licensing bureau  URL is state specific	F  V  A  C  F

Agencies charged with enforcement of medical waste incinerators	Medical waste program	State plan  Environmental quality of some type	URL is state specific	F M F v ii
<b>State-Plan-State</b>  Occupational Safety and Health Acts	OSHA  Occupational health, radiation health	State plan  Occupational Safety and Health	URL is state specific	F  E e T
Labor Department or Occupational Safety, Health Act	General safety  Labor: general safety program	State plan  Labor division	URL is state specific	F  S  V c L
<b>Local</b>  <b>Local health department</b>	Jurisdiction may be separate from state health departments	Communicable disease agency	URL is state specific and may have local links	F  C c a
Fire marshal; water jurisdiction	Departments of public health or city	Food, water, waste	URL is state specific and may have local links	F  I f c e

**\*AHJ = Authority Having Jurisdiction.**

**HHS = organizational chart accessed February 2, 2009: <http://www.hhs.gov/about/orgchart/>.**

## Department of Health and Human Services

### Centers for Disease Control and Prevention

The CDC's mission is to collaborate to create the expertise, information, and tools that people and communities need to protect their health—through health promotion; prevention of disease, injury, and disability; and preparedness for new health threats. The CDC seeks to accomplish its mission by working with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training.<sup>4</sup> The CDC responded to a national anthrax mail

scare in 2001 and continues to provide critical direction and leadership for all aspects of programs involving bioterrorism and related agents, such as preparing for pandemic influenza. The Emerging Pathogens program has developed important initiatives in recent years, ranging from study of new pathogens to that of new levels of antimicrobial resistance, for example, vancomycin-resistant *Staphylococcus aureus*. The CDC provided major leadership with the World Health Organization in responding to the SARS epidemic, identifying a new variant of corona virus with enormous public health implications around the world. As noted in Table 4-1, the CDC has important advisory committees; the Healthcare Infection Control Practices Advisory Committee (HICPAC) publishes a number of infection prevention guidelines that are applied to appropriate settings. Although many consider their recommendations "standard setting," they are not regulatory in nature nor are they enforced as regulatory standards. However, CMS and TJC, as well as other accrediting agencies, base their enforcement activity on these gold standard guidelines. Another advisory committee important to infection prevention and control programs is the Advisory Council for the Elimination of Tuberculosis, which is closely related to tuberculosis prevention guidelines. Several key divisions and committees within the CDC are described here.

### *The Division of Healthcare Quality Promotion (Formerly the Hospital Infections Program)*

The CDC's DHQP is one of seven divisions within the National Center for Emerging and Zoonotic Infectious Diseases and is composed of one activity (program implementation and integration), the Immunization Safety Office, and three main branches: Clinical and Environmental Microbiology Laboratory, Prevention and Response, and Surveillance. Among these activities, DHQP (1) conducts research, surveillance, investigations, and laboratory and field studies of HAIs, as well as research on methods of preventing and controlling infections; (2) collects and processes clinical and environmental specimens; (3) rapidly diagnoses disease and identifies unusual sources of infection; (4) evaluates medical devices as sources of infection; and (5) analyzes and reports antimicrobial resistance.

- **Dialysis:** DHQP has primary responsibility for the prevention of dialysis-associated disease, including guidance for equipment disinfection and other means of prevention of disease transmission. The Dialysis Surveillance Network (DSN), a voluntary national surveillance system monitoring bloodstream and vascular infections in adults and pediatrics, was initiated by the CDC in 1999.
- **Disinfection and sterilization:** DHQP develops disinfection and sterilization procedures and recommends broad strategies for proper use of sterilants, disinfectants, and antiseptics to prevent the transmission of infection in the healthcare environment. This includes both environmental and medical device issues.
- **National Surveillance of Nosocomial Infections and National Healthcare Safety Network:** National Surveillance of Nosocomial Infections began in 1970 and was conducted through DHQP's National Nosocomial Infections Surveillance System (NNIS) to estimate the magnitude and nature of HAIs and to provide hospitals with comparative data to evaluate prevention and control efforts. DHQP has incorporated NNIS into a Web-based knowledge system identified as the National Healthcare Safety Network (NHSN), which accumulates, exchanges, and integrates relevant information and resources to protect patients and promote healthcare safety. NHSN includes the elements of NNIS, National

Surveillance System for Healthcare Workers, and DSN (see "Dialysis" above), forming an integrated data repository at the CDC. With the explosion of state-mandated public reporting, NHSN is now used in more than 11,000 hospitals across the United States and is expected to grow further, including more focus on electronic capture and transfer of information within HHS.

- Bloodborne pathogens: DHQP conducts studies on the nature, frequency, and risk factors for transmission of bloodborne pathogens in healthcare and develops guidelines to reduce these risks.

### *Division of Healthcare Quality Promotion-Healthcare Infection Control Practices Advisory Committee (Formerly Hospital Infection Control Practices Advisory Committee)*

HICPAC was established in 1991 to provide guidance to the CDC and develop guidelines on specific infection prevention practices in healthcare. Guidelines are published cooperatively on the CDC website and in professional journals, including the *American Journal of Infection Control*. Drafts are usually published for comment in the *Federal Register*. The guidelines are used as major resources for policy development and modified for facility-specific needs; they are not regulatory in nature but healthcare organizations will generally be expected to justify practices that deviate from established guidelines. In light of the intense federal and state attention to preventing and controlling HAIs, HICPAC has taken a lead role within the HHS HAI action plan and has been streamlined into an important communication role among HHS, CDC, and the healthcare community.

### *National Center for Immunization and Respiratory Diseases-Advisory Committee on Immunization Practices*

Advisory Committee on Immunization Practices (ACIP) was established in 1964 to provide guidance to the CDC's National Center for Immunization and Respiratory Diseases on the most appropriate application of antigens and related agents (e.g., vaccines, antisera, and immunoglobulins), as well as to recommend specific immunization practices and strategies to improve national immunization efforts. Recommendations are published and updated in the *Morbidity and Mortality Weekly Report (MMWR)* as well as in periodic *MMWR Recommendations or Summaries*. The 2011 *Immunization of Health-Care Personnel guideline (MMWR 60 No.7)* for healthcare personnel was a joint initiative between ACIP and HICPAC.

### *The National Institute for Occupational Safety and Health*



NIOSH was established by the 1970 Occupational Safety and Health Act. This agency conducts research on occupational hazards, provides technical assistance and recommendations to OSHA, and participates in the training of occupational safety and health experts. However, its charge is based on a premise of determining "zero" risk of exposure, without being compelled to determine the cost/benefit of required interventions. Enforcement agencies such as OSHA may accept or reject recommendations from NIOSH. NIOSH has had a major impact on developing personal protective equipment guidance, including respiratory protection.

### *The Agency for Toxic Substances and Disease Registry*

ATSDR is responsible for providing leadership and direction to programs and activities designed to protect both the public and healthcare personnel from exposures to hazardous substances. Safety committees are familiar with its expertise and leadership in developing emergency preparedness programs. A notable activity of ATSDR involved medical waste and resulted in the 1990 report to Congress, "The Public Health Effects of Medical Waste." The agency concluded that the general public is not likely to be adversely affected by medical waste generated in the traditional healthcare setting.

### THE U.S. FOOD AND DRUG ADMINISTRATION

The FDA develops, implements, monitors, and enforces standards for the safety, effectiveness, and labeling of all drugs and biologics, including food, blood and blood products, medical and radiological devices, antimicrobial products, and chemical germicides used in conjunction with medical devices. Some confusion among the agencies with overlapping jurisdictions (FDA, EPA, and OSHA) for chemicals was addressed through memoranda of understanding related to enforcement concerns. Historically, the EPA was the organization in the federal government that registered new chemical sterilants. There were approximately 40 formulations approved in the United States. Following the agreement between the EPA and FDA that sterilants and high-level disinfectants that were intended for use on medical devices would be the responsibility of the FDA, the FDA required all such products to be cleared by the 510(k) process. As a result, there are fewer formulations on the market. The FDA enforces final regulations governing reuse of single-use devices, leading to hospitals' almost exclusive use of third party reprocessing companies that must follow specific criteria from the FDA.

- Blood safety: The FDA is responsible for the safety of the nation's blood supply. The FDA has specific standards for collection, testing, and distribution of blood, as well as disposal of contaminated or untested blood. These standards apply to all facilities that have blood banking operations and are being comprehensively revised.
- Chemical germicides: The FDA regulates chemical germicides that are formulated as antiseptics, preservatives, or drugs to be used on or in the human body, or as preparations to be used to inhibit

microorganisms on the skin. Based on data voluntarily provided by the manufacturer, chemical germicides are divided into three categories: category I, safe and effective; category II, not safe or efficacious; and category III, insufficient data to categorize. Chemical germicides, when used in conjunction with specific medical devices, may also require FDA approval.

- Medical Device Act (1974) and Safe Medical Device Act (SMDA) of 1990: The Medical Device Act of 1974 required the classification of medical devices according to their potential to cause harm. The SMDA of 1990 expanded the FDA's authority in this area by improving incident reporting, removing defective or dangerous devices in a timely manner, and ensuring that only safe and effective devices enter the marketplace.

## THE HEALTH RESOURCES SERVICE ADMINISTRATION

HRSA provides leadership and support efforts to integrate health service delivery programs with the public and private financing programs.

- National Practitioner Data Bank: Created as part of the Health Care Quality Improvement Act of 1986, the database collects and disseminates information concerning adverse actions affecting physicians, dentists, and other healthcare professionals. Hospitals are required to report adverse disciplinary actions against practitioners, query the data bank every three years, and query again at the time of medical staff appointment.
- Organ Procurement: HRSA administers grant-supported programs such as operation of the Organ Procurement and Transplantation Network.
- Hospital preparedness and public health infrastructure funding: In the years following 9/11, HRSA provided funding to states to enhance hospital and regional preparedness efforts. In 2006, the National Bioterrorism Hospital Preparedness Program was transferred from the HRSA to the Assistant Secretary for Preparedness and Response.

## AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ is an agency developed by Congress to define the appropriateness or necessity of medical care. It was formerly known as the Agency for Healthcare Policy and Research and was reauthorized in 1999 by the Healthcare Research and Quality Act. Its mission is to assess and enhance the quality of medical care through outcomes research and development of clinical practice guidelines. The role of this office has taken on a new dynamic with the 1999 publication of the Institute of Medicine's *To Err Is Human: Building a Safer Health System*.<sup>2</sup> AHRQ was given the charge to coordinate all federal quality

improvement efforts, provide health services research oversight, and lead this effort through the Quality Interagency Coordination Task Force. Within the new HHS-HAI Action Plan, AHQR focuses knowledge transfer of CDC/HICPAC-approved guidelines.

## NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH), with its 27 specialized institutes and centers, is responsible for improving the health of the nation. NIH is the world's largest biomedical research organization and maintains the National Library of Medicine, the world's largest center of medical literature.

## CENTER FOR MEDICARE & MEDICAID SERVICES (FORMERLY, HEALTH CARE FINANCING ADMINISTRATION)

CMS was established by HHS in 1977 and is responsible for oversight and reimbursement monitoring of Medicare and Medicaid programs. Its regional offices maintain close working relationships with state health departments for enforcement activity.

- Infection control standards and Medicare/Medicaid: CMS maintains independent standards for infection prevention in hospitals, long-term care, and home care facilities/agencies and enforces compliance with these as conditions for certification and participation (CoP) in Medicare and Medicaid Programs. The Infection Control Interpretive Guidelines for each of these settings undergo periodic review and APIC works with CMS to provide input for hospitals, long-term acute care hospitals (LTACs), long-term care (LTC), ambulatory surgical centers (ASCs), and home health services.
  - Acute care: The most recent update to the CoP affecting infection prevention was the release of the infection control interpretive guidelines published in 2008. New emphasis is being placed on performance standards and outcome measurements (e.g., HAI rates).
  - LTAC: LTACs must meet Medicare's CoP for acute care hospitals and have an average inpatient length of stay longer than 25 days.
  - LTC: Nursing homes were required in 1998 to transmit data electronically to CMS on each patient in a set of assessments termed *Minimum Data Set* (MDS). This covers all aspects of patient care, including infections. LTC must now provide online "report cards" similar to the acute care "Hospital Compare" website to inform the consumer of their performance. In 2012, CMS released a *Nursing Home Action Plan*, which included increased focus on HAI in the survey process.
  - Ambulatory care: CMS updated its infection control interpretive guidelines for ambulatory surgical centers in 2009. In January 2012, CMS required dialysis facilities participating in the End-Stage Renal Disease Quality Incentive Program to report certain infection events to the NHSN. Under the Ambulatory Surgical Center Quality Reporting program, ASCs report quality of care data for standardized measures to receive the full annual update to their ASC annual payment rate, beginning in 2014.
  - Home health services: CMS issued a final rule addressing the Home Health Prospective Payment System in 2013, which discusses the transition in ICD-10 coding and establishes home health quality reporting requirements for subsequent years.
- Construction: Construction codes and standards for physical plant/environmental standards were revised with a new requirement for infection prevention input. CMS does address the physical plant in its *CoP for the Physical Plant*. However, HHS provides support to the development of design and construction guidelines used by most states and published by the Facility Guidelines Institute and the

American Society of Healthcare Engineering of the American Hospital Association. Hospital construction and costs are directly related to the charge of CMS's mission. Although CMS does not adopt the guidelines as regulations per se, the agency does concur with the recommendations. Nearly every state adopts the guidelines as a whole or may adapt it as a basis for their own state codes. CMS enforces construction codes or the guidelines through health department surveyors as agents of CMS for CoP in Medical and Medicaid. The guidelines have expanded requirements for a documented "infection control risk assessment" (ICRA). After a basic ICRA was first published by the American Institutes of Architects in 1996, the most recently updated version now includes many issues beyond the determination of needed number of airborne infection isolation rooms. The ICRA addresses both design and selection of materials, as well as mitigation processes during construction or renovation.<sup>5</sup>

- **Deemed status and state exemptions:** Healthcare facilities accredited by TJC, a voluntary agency, are deemed to be in compliance with CMS requirements and are exempted from routine federal or state inspections. CMS follows and validates approximately 5 percent of accredited hospitals following a facility survey. State health department surveyors enforce CMS CoP in Medicare/Medicaid in facilities that have foregone voluntary accreditation, whether TJC, the American Osteopathic Accreditation's Healthcare Facilities Accreditation Program, or Det Norske Veritas Healthcare Inc. (DNV). DNV's accreditation program, called the National Integrated Accreditation for Healthcare Organizations (NIAHO), integrates the International Organization for Standards' ISO 9001 quality management system standards with the Medicare conditions of participation. NIAHO is the first accreditation program to integrate hospital accreditation with ISO 9001.
- **Medicare Quality Improvement Organizations, formerly known as State Peer Review Organizations:** Quality improvement organizations operate under contract with CMS to ensure that medical services provided to Medicare patients in hospitals and certain outpatient settings are medically necessary and appropriate and meet recognized standards of care. Their approach has been moving from individual performance to that of trending and outcome measurements in line with CMS requirements. These organizations are key for collaborative efforts in developing and publishing public performance measures.
- **Clinical Laboratory Improvement Act:** In 1988, Congress passed legislation (CLIA 88, 42 CFR 493) to amend the Clinical Laboratory Improvement Act (CLIA) of 1956. CMS issued final regulations to implement the statutory authority granted by CLIA, and extend the scope of CLIA to all laboratory testing, including physician office labs and clinics, and mandate specific personnel, proficiency testing quality control, patient tests, management, and computer systems. There is no umbrella organization coordinating the standardization of accreditation standards of all entities awarding CLIA certificates. States typically enforce CLIA through CMS licensing and certification divisions of state health departments.

## Independent Federal Agencies

### Environmental Protection Agency

The EPA is an independent agency responsible for regulation and registration of chemical germicides formulated as sterilants and disinfectants used on devices or environmental surfaces as part of the Federal Insecticide, Fungicide, and Rodenticide Act.

- **EPA and FDA germicide responsibilities:** The EPA and FDA have entered an interagency agreement to jointly test all registered sterilants, those products seeking registration, and those products

(sterilants and hospital-type disinfectants) making unsubstantiated claims about controlling tuberculosis. Information regarding products and their approval status is routinely available from the EPA's hot line, both by fax and on the Internet.

- Resource Conservation and Recovery Act (RCRA): Through the RCRA of 1976, the EPA was designated the authority for developing regulation for management of solid waste, including regulated medical waste. To this day there is no comprehensive federal policy on medical waste. Regulations are driven by each state and interaction with the Department of Transportation. New attention to pharmaceutical waste disposal as part of general concerns on the environment may involve infection prevention and control programs.
- Incinerators and medical waste: The EPA has published regulations on medical waste incinerators regarding emissions control and ash disposal as part of recent revisions of the Clean Air Act.

## Occupational Safety and Health Administration-U.S. Department of Labor

OSHA is a division of the U.S. Department of Labor. Its programs are administered under the jurisdiction of the federal Occupational Safety and Health Act and through approved state plans.

- General duty clause: Basic to OSHA's activity is the general duty clause of the 1970 Occupational Safety and Health Act requiring that an employer is responsible for providing a workplace free of occupational hazards. Specific standards are developed according to identified hazards, and compliance documents are developed to interpret the standard. State level OSHA plans may have additional requirements beyond the federal requirements.

### *BLOODBORNE PATHOGEN RULE*

Publication of the bloodborne pathogens rule in 1991 was the first to address specifically infection-related activity and, in 2001, OSHA published a revision to the bloodborne pathogen standard. The new requirements included: an expanded definition of engineering control to include devices with engineered sharps injury protection and needleless systems; exposure control plans that reflect changes in technology that reduce exposure to bloodborne pathogens and document the consideration, at least annually, of devices to minimize occupational exposure; solicitation of input from nonmanagerial (i.e., frontline) healthcare personnel for identification, evaluation, and selection of devices and other controls that is documented in the exposure control plan; and maintenance of a sharps injury log of percutaneous injuries with information on the type and brand of device involved, the department where the incident occurred, and an explanation of how the injury occurred.

### *TUBERCULOSIS*

In the event that a newly identified hazard does not have an existing standard (e.g., tuberculosis [TB]), OSHA develops an emergency compliance document to interpret and enforce compliance under the general duty clause. The documents can be requested from the agency and are available on the OSHA website. Although a TB standard had been proposed in 1997, OSHA withdrew the proposal because it did not meet the criteria to justify promulgation of a standard. OSHA's revised Respiratory Protection Standard (29 CFR 1910.134 and 29 CFR 1926.103) went into effect in 1998. The 29 CFR 1910.139 respirator standard that applied only to respiratory protection against *Mycobacterium tuberculosis* was withdrawn December 31, 2003. Establishments' respiratory protection programs for TB (formerly covered under 29 CFR 1910.139) were required to adapt to comply with the requirements of 29 CFR 1910.134, effective July 2, 2004. The major change was to require annual fit testing in addition to the initial fit testing already under way by hospitals. OSHA resumed enforcement of this change in 2008.

- **APIC's advocacy role:** It is worth noting that APIC played an important role in several aspects of TB enforcement issues. APIC was successful in collaborating with many associations to provide data leading to the withdrawal of the TB standard as noted. APIC also led a coalition to address the lack of science that justified the need for annual fit testing of N95 respirators, collaborating with Representative Wicker to add an amendment (or rider) to the annual appropriations bill preventing OSHA from spending federal dollars to enforce that component of the respiratory protection standard. For several years the rider, aptly named the Wicker Amendment, barred OSHA from enforcing annual fit testing. APIC, along with more than a dozen organizations, supported reinstatement of the amendment because of the lack of scientific evidence that annual fit testing, an expensive mandate, decreased the risk of healthcare personnel exposure to TB. The U.S. House of Representatives Appropriations Committee rejected the amendment in the 2008 appropriation bill, reinstating OSHA's enforcement action for annual fit testing.
- **Compliance inspection:** OSHA conducts inspections of healthcare facilities on a predetermined schedule, and in response to a serious hazard or as a result of an employee complaint. Recently, the agency has developed a targeted approach, focusing on injuries of high frequency and seriousness in specific industries. In those regions with state-level OSHA plans, implementation of the OSH Act may be under the jurisdiction of different agencies within the state. Standards and compliance with those standards developed within states must be at least as effective as federal OSHA. Many states adopt the specific federal standard by reference.
- **Occupational illness/injury logs:** OSHA issues regulations to protect healthcare personnel from occupational illness and injury. Recent standards have addressed hazard communications (chemical exposure), bloodborne pathogens, and ergonomics.

## United States Department of Agriculture; Food Safety Inspection System

The USDA has responded to increasing reports of problems of food contamination and consumer demand for safer food products following outbreaks of pathogens, for example, *Escherichia coli* O157:H7, Hepatitis A, and antimicrobial-resistant microorganisms. Specific program initiatives are collected and managed under the program of Hazard Analysis Critical Control Points. More information is available from USDA Food Safety Inspection Service through its online resources.

## Department of Transportation; Research and Special Programs Administration

Although the DOT has broad responsibility for ensuring safe transport of goods, the Research and Special Programs Administration (RSPA) has important linkages to regulated medical waste (RMW) and its transport across state lines. Although definitions and management of RMW disposal are under the jurisdiction of the EPA, as discussed, the DOT raised major concerns in waste management industries when it proposed regulations using performance-oriented packaging standards for RMW. The DOT promulgated its final regulation in 1996 using criteria-based definitions, and its final packaging and labeling requirements remain consistent with the OSHA bloodborne pathogens standard. The regulation allows an exemption for laboratory cultures and stocks by subjecting them to stringent packaging requirements. Another exemption of importance to infection preventionists is that related to transport of laundry and medical devices as long as procedures conform to OSHA bloodborne pathogens regulations. In the *Federal Register* of September 1998 (63; 1700), the RSPA published proposed further revisions to its packaging standards: "Hazardous materials: Revisions to standards for infectious substances and genetically modified microorganisms" (49 *CFR* Parts 171, 172, 178, and 183). The proposal considers revising the standards, including RMW, to adopt defining criteria, hazard communication, and packaging requirements for Division 6.2 materials consistent with international standards. The revision was also to revise broad exceptions for diagnostic specimens and biological products and improve safety and ease in understanding the regulations. Input was solicited in an



electronic public meeting in September 2002, and the final outcome was published for enforcement in February 2003. The major impact is actually on the waste hauling companies, with new requirements focusing on packaging. Healthcare requirements involve requirements for education of staff managing waste.

## CONGRESSIONAL INFORMATION AGENCIES

### Government Accounting Office

The GAO, an agency of the legislative branch, is responsible for providing Congress with information on expenditures and financial management issues at the request of Congress. One report evaluated infection prevention and control programs in the Department of Veteran Affairs (VA) and a sample of non-VA hospitals. The GAO report *Cost and Benefit of Needlestick Prevention* (GAO-01-60R) estimated the cost-effectiveness of sharps with safety features. Others have assessed the government's bioterrorism preparedness and smallpox vaccination programs. As noted, the GAO has done several reports on HAI-related topics, including medical device reprocessing, HAI reporting, and coordination of HAI reduction efforts within the HHS. Published reports are available through the U.S. General Accounting Office, PO Box 6015, Gaithersburg, MD 20877 or on the GAO website. Others can be identified and ordered through online resources. (See Table 4-1.)

### Voluntary Accreditation Agencies

A number of accreditation agencies have considerable effect on healthcare organizations, and the resulting certification has implications for both marketing and reimbursement of funding, if accreditation or "deemed status" is at stake. (See "CMS" section.)

### Healthcare Facility Accreditation Organizations

The Joint Commission (TJC), formerly known as the Joint Commission on Accreditation of Healthcare Organizations, was established in 1915 as a hospital standard-setting program of the American College of Surgeons (ACS). The first hospital inspections were performed by the ACS in 1918, based on the *ACS Minimum Standard for Hospitals*. In 1951, the ACS joined with the American College of Physicians (ACP), the American Hospital Association (AHA), the American Medical Association (AMA), and the Canadian Medical Association (CMA) to form the Joint Commission on Accreditation of Hospitals (JCAH), an independent, not-for-profit organization whose primary purpose was to provide voluntary accreditation. In 1952, JCAH took over the hospital standardization program from ACS and, in 1953, it published the *JCAH Standards for Hospital Accreditation*. With the passage of the Medicare Act in 1965, the role of JCAH shifted, becoming more closely tied with government. The law provided that hospitals accredited by JCAH were "deemed" in compliance with most of the Medicare CoP for Hospitals and, thus, were deemed eligible to participate in the Medicare program. Currently, the ACP, the AMA, the AHA, the ACS, and the American Dental Association (ADA) govern TJC.

The American Osteopathic Association provides a similar accreditation to hospitals, known as the Healthcare Facilities Accreditation Program. As discussed in "CMS, Deemed Status and State Exemptions," a third organization, Det Norske Veritas Healthcare Inc. (DNV), was approved by CMS in 2008 to provide an accreditation program called National Integrated Accreditation for Healthcare Organizations.

- Accredited organizations and TJC initiatives: A variety of healthcare organizations beyond just hospitals (e.g., ambulatory care clinics, long-term care, home care, laboratories) are accredited by TJC. Standards and scoring guidelines are published annually, and a 3-year accreditation is awarded to hospitals found to be in compliance. Major changes in the accreditation process began in 2003

under the initiative "Shared Visions—New Pathways." By 2004, organizations were doing their own periodic performance review midway in their review cycle, followed by the actual survey. As of 2006, unannounced surveys were routine. The new processes required major streamlining of standards to ensure each element is scorable. During this process, the Infection Control Standards were revised with major input from infection prevention experts. HAIs received increased attention from TJC when it announced that reduction of HAIs would be added as the latest NPSG for 2004 and further expanded in the 2009 standards. HAIs have continued to figure in a major way in current NPSG, and compliance relies heavily on implementation of the CDC's hand hygiene guidelines, as well as major infection prevention guidelines, such as catheter-associated bloodstream infections, surgical site infections, and prevention of multidrug-resistant organisms.

- **Indicator Measurement System (IMS):** As part of its "agenda for change" during the 1990s, the TJC began a long-term project to develop quantitative indicators measuring certain aspects of quality patient care. These indicators were to have been built into the TJC's IMS, which was national and voluntary. However, after massive testing of the system, the IMS indicators were changed considerably and developed into another initiative known as ORYX.
- **ORYX and core measures:** During 2003, the ORYX initiative (not an acronym but a term coined by the TJC for this project) began a replacement into sets of measurements termed core measures. This latest set of indicators is aligned with CMS initiatives overseen by state quality improvement organizations, as well as with AHQR measures and others proposed by organizations in the private sector. The intent is alignment of mandatory and voluntary quality measures and standardized definitions. Indicators important to infection prevention efforts, such as surgical care, pneumonia, and immunization, are included.

## Laboratory Inspection and Certification

The College of American Pathologists (CAP) conducts voluntary inspections and certifications of laboratories. In addition, CAP performs quality control studies using research to improve laboratory performance. These are done every two years with laboratories carrying out self-surveys in the nonsurvey year. Successful surveys may provide deemed status for laboratories also accredited by TJC. However, TJC surveys continue to review broad laboratory performance improvement measures in which the laboratory interacts with the rest of its affiliated healthcare organization, beyond basic CAP quality control measures. The Commission on Office Laboratory Accreditation is another laboratory accrediting agency affecting offices and clinics and is also recognized by TJC. TJC has also entered into another collaborative accreditation effort with CAP and the American Proficient Institute (API) termed the Lab Advantage, which emphasizes a quality improvement approach.

## Other Accrediting Organizations

Other well-known organizations accredit specific entities, such as health maintenance organizations, clinics, and offices, for example, National Committee on Quality Assurance (NCQA) and the American Medical Accreditation Programs (AMAP). Along with TJC, NCQA, AMAP, and DNV are the preeminent healthcare accrediting organizations. NCQA is recognized as one of the top organizations providing voluntary accreditation for managed care organizations—that is, health maintenance organizations (HMOs). HMOs primarily measure outcomes in an ambulatory care setting. NCQA has developed a summary of measures known as Health Plan Employer Data and Information Set (HEDIS), which is increasingly used as an outcomes report. HEDIS includes important preventive measures of health, for example, immunization rates. TJC, NCQA, and AMAP have developed a Performance Measurement Coordinating Council (PMCC) to ensure efficiency and consistency in their activities within these various organizations. Infection-related surveillance outcomes should be considered in each of these initiatives.

The Commission on Accreditation of Rehabilitation Facilities (CARF; [www.carf.org](http://www.carf.org)) provides voluntary accreditation to facilities meeting their standards for quality in the United States, Canada, and Europe.

## State and Local Agencies

### State Agencies

States have multiple departments that parallel functions of the federal agencies outlined here—that is, jurisdictions related to health, education, welfare, environment, agriculture, and so forth. The organizational structures vary by name and grouping of functions or programs; linkage to federal programs occurs frequently through funding or regulatory requirements. For example, OSHA administers occupational health and safety programs in many states, but at least 27 states have independent OSHA programs. State-plan state programs must provide enforcement that is at least as effective as that of OSHA. Infection preventionists should identify the agencies in their region that establish laws, rules, and regulations for healthcare facilities, as well as for professional licensure, certificate of need, and environmental regulations, such as medical waste or management of pesticides. Designated state agency surveyors act as agents of CMS to enforce the CoP for Medicare and Medicaid within states and are linked to federal agencies through regional offices. These affect healthcare service delivery processes and design standards for healthcare facilities, as discussed. Interaction with state and local agencies has become increasingly important for bioterrorism program planning as well.

### Local Jurisdiction

Infection preventionists also need to familiarize themselves with public health and education laws regulated by specific state and local health departments. Regulations for reportable communicable diseases vary from state to state regarding what reporting is required and how reporting should take place. The regulations include reporting of laboratory-based infectious agents and clinical diseases and may also define processes for reporting outbreaks and related interventions. State-regulated healthcare construction codes may be influenced or modified by local authorities having jurisdiction over issues such as water quality, levels of discharged contaminants, and local fire marshal regulations. (See Table 4-1.)

## Clinical Practice Guidelines

Efforts to contain costs have heightened consumer desire for information about healthcare quality and value. Purchasers of healthcare demand information about providers and the care delivered compared to accepted clinical practice guidelines and standards.

### American College of Physicians and Practice Guidelines

The American College of Physicians defines *practice guidelines* as a means of providing knowledge derived from a scientific analysis of the practice of medicine, in a useful format to physicians, patients, and others, about the best use of healthcare resources. As part of the information management and quality improvement, healthcare facilities integrate practice guidelines into their professional credentialing activities. The TJC is developing new standards requiring hospitals to consider their use when measuring patient care management.

### Consumer Resources

By the mid-1990s, more than 60 professional organizations had developed well beyond 1,500 practice guidelines raising concern about focus, resources, and scientific validation.<sup>3</sup>The Performance

Measurement Coordination Council may be a start in grappling with consistency and efficiency. However, consumer demand and purchaser pressure for accountability related to healthcare costs led to increased frequency of public reporting of outcome measurements. Data began being published by facility and physician name in many areas of the United States by the late 1990s. These measurement "report cards" may ultimately lead to improved efforts of validation and better resource utilization. As noted, the American Hospital Association, in collaboration with other organizations, such as TJC and HHS, announced an initiative identifying a set of common indicators that are published as a public report card of all hospitals (Healthcare Quality Alliance [HQA]) similar to CMS efforts in nursing homes and home care. The "Hospital Compare" website (<http://www.medicare.gov/hospitalcompare/>) reports quarterly on all hospitals' performance and annual hospital reimbursements are dependent on hospitals reporting on all required indicators. In addition, many states have also passed legislation making hospital performance and infection prevention outcomes data publicly available.

## Professional and Trade Organizations

Numerous healthcare professional and trade associations have influenced hospital infection prevention and control programs with the development of guidelines and standards on various aspects of infection prevention practice. Although these groups are voluntary, they often become the standard of practice for governmental and accreditation bodies. Several organizations have also published journals dedicated to hospital epidemiology and infection prevention practice to provide a forum for exchange of scientific and professional information.

APIC provides published guidelines and resources, as well as online resources to inquire about or research existing standards and practices. The Certification Board in Infection Control and Epidemiology Inc. offers professional certification in infection control. APIC maintains a Practice Guidance Council whose members act as formal, active liaisons to multiple professional organizations with overlapping interests leading to joint collaborations on common issues. The breadth of interests is illustrated with a few examples: Association for the Advancement of Medical Instrumentation, a critical source of standards for sterilization practices; Association of Peri-Operative Registered Nurses; American Society of Testing and Materials; AHA's personal membership groups, such as the American Society of Healthcare Environmental Services; CDC's Healthcare Control Practices Advisory Committee (CDC/HICPAC); TJC; NQF; and the United States Pharmacopeia. APIC's Emergency Preparedness Committee interacts with many federal and state associations, and APIC's public policy and governmental affairs staff assist members in developing collaboration and coalition building with many professional groups with similar interests and alliances.

An excellent example of this collaboration was the publication in 2008 of an important set of implementation strategies: *A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*.<sup>6</sup>This series of implementation strategies was developed by the Society of

Healthcare Epidemiology of America (SHEA) and the Infectious Disease Society of America (IDSA) in partnership with APIC, AHA, and TJC. The compendium was developed from the CDC's four basic HAI guidelines described earlier plus two epidemiologically significant organisms: MRSA and *C. difficile*. CDC/HICPAC had reviewed and provided input and worked with SHEA/IDSA to develop an accompanying set of practical patient guides for the consumer, built on the same guidelines. Another recent example of collaboration between professional organizations is the 2013 *Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery*, developed jointly by the American Society of Health System Pharmacists, the Surgical Infection Society, IDSA, and SHEA.



## International Perspective

This chapter addresses organizations that have an impact on infection prevention and control programs in the United States. Infection prevention and control programs worldwide are guided by local and regional regulatory and accrediting groups. Additional information on region-specific regulatory bodies can be accessed through infection prevention and control organizations, such as the Infection Prevention and Control Canada (IPAC Canada), the Infection Prevention Society (IPS) in Britain, and the International Federation of Infection Control (IFIC). The World Health Organization publishes healthcare infection prevention and control guidelines, with the goal of assisting in the assessment, planning, implementation, and evaluation of national infection prevention and control policies and guidelines.

## Conclusions

Effective infection preventionists function through a variety of multidisciplinary activities within all healthcare delivery settings. Organizations rely on infection preventionists to understand the related accrediting and regulatory requirements and to recommend policy and actions based on current standards and guidelines. Continuous changes require IPs to remain current in the regulatory milieu to maintain an effective and credible program, regardless of the care setting.

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# Infection Prevention and Behavioral Interventions

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## Abstract

*As is the case with patient care treatment regimens, infection prevention processes in healthcare institutions are often reliant on healthcare personnel's compliance with behavioral recommendations. This chapter reviews the application of behavioral science theories as a guide for planning new or improving existing strategies to prevent the spread of healthcare-associated infection. It also suggests some general principles including environmental strategies to apply when developing educational programs and campaigns purposed to change behavior.*

## Key Concepts

- Programs to influence the human behavior aspect of infection prevention must be strategically planned, with reference to relevant behavioral science theories.
- Behavioral science theory applied in infection prevention can make practitioners more efficient and effective by helping them focus on factors likely to be important while avoiding investment of time and resources into factors unlikely to be important.
- The body of human behavior theory is very large and growing. Although theories presented in this chapter are only a small number of the whole, they are selected because they are widely used and tested in diverse settings for a range of behavioral challenges.
- Even with sophisticated theoretical underpinnings and best practice implementation, behavior change theories are rarely fully successful. The current state of health promotion and behavior theory application is not sufficient for the complexity of most behavioral challenges, including those in healthcare environments. Use of theory will improve our success, not assure total victory over behavioral problems.
- A focus on behavior change must be supported by organizational policies and procedures and environmental strategies to enhance the effect obtained by behavioral strategies implemented through infection prevention and control programming.



# Background

How could it be possible that in a society with abundant medical technology, well-trained clinicians, and widespread access to healthcare that a key problem in treating illness is the failure of patients to take prescribed medication leading to more than \$100 billion dollars in unnecessary healthcare costs annually?1How could it be possible that after generations of warnings from health professionals about one in five adults in the United States still smoke cigarettes?2How could it be possible that with widespread understanding among healthcare personnel regarding the means of transmission of healthcare-associated infections (HAIs), there is extensive failure to practice effective hand hygiene in hospitals and nursing homes?3These paradoxes illustrate the fact that our stunning progress in medical science and engineering has far outstripped our understanding of the dynamics of learning and human behavior.

Heifetz has identified two types of challenges when implementing change: technical and adaptive. "Technical is defined as those that can be solved by the knowledge of the experts, whereas adaptive requires new learning."4Technical work is easier than adaptive work. Yet, as the "what," it is only about 20 percent of the change. Adaptive work, the greater percentage of transition, is the "how"—where the community that needs to change must engage in the process, overcome resistance, and put new wisdom into practice. Infection preventionists (IPs) have been far too simplistic in their approach to addressing the human factors of healthcare, whether the focus is on the educational component of patient care or advancing the adoption of best practices among healthcare personnel.

Programming, either directed at patients or healthcare personnel, should be strategically planned. That is, at the very least, the planner should articulate what it is they want people (the target group) to do. Table 5-1 has examples of potential behavior change objectives pursued by IPs. With the starting point of a behavioral objective, IPs can then work backward to analyze all the factors that must be addressed in order for that behavior to take place in the target group. Some of the factors will be self-evident from tried and true clinical practice, whereas some factors are established after a thorough research effort. It is easy to find examples of "conventional wisdom" that turned out to be incorrect. Nevertheless, thoughtful and resourceful IPs can sometimes solve problems without reference to sophisticated theories or rigorous clinical trial and error evaluation. Courageous leaders in infection prevention will ask hard questions to be sure what passes for routine practice is ultimately evidence based, not just a matter of tradition and convenience.

**Table 5-1 Behavioral Objectives Relevant to Infection Prevention Practice**

By the end of the next six months, 80% of the hospital's staff working in general patient areas will be following hand hygiene best practice all or almost all of the time.
By the end of the next six months, 95% of the hospital's staff working in surgical suites will be following hand hygiene best practice all or almost all of the time.
By the end of the next six months, 95% of the hospital's staff working in intensive care (ICU/CICU/NICU) units will be following hand hygiene best practice all or almost all of the time.
By the end of the next six months, 75% of the managed care organization patients directed to take antibiotics will be taking their medications correctly and for the proper duration.
By the end of the next six months, 90% of clinicians will use correct gloving techniques when at risk for exposure to patient bodily fluids all or almost all of the time.

Perhaps more times than not, when IPs are seeking to modify behavior among patients or healthcare personnel, it will not be obvious what factors should be addressed. For many years, it was not apparent what factors were important to help smokers quit or to support a diabetic patient's compliance to diet. Painful experience has taught that giving people more information about their smoking, about their

diabetic diet, or about their infection will often not result in desirable behavior change. In this common void of not being sure what will work, behavior change theory can provide a useful guide.

## Basic Principles

In everyday experience, conversations often start with the phrase, "My theory on that is ..." followed only by someone's homespun hunch about the way of the world. Although this makes for stimulating talk between friends and coworkers, the point of discussion is not really theory in a scientific sense. Behavioral science theories used in health promotion are not the product of water cooler banter, but based on rigorous testing of components (or constructs) of a researcher's ideas. Scientific behavioral theories have a long gestation period, during which the research team will carefully add, subtract, and modify factors, always working toward a better way to predict how people will act in a given set of circumstances. Put another way, the researchers seek to find the most ideal circumstance composed of factors that will bring about the greatest change in people's behavior.

The end result of this work is to be able to define strategies that have proven successful in facilitating people to adopt desirable health-related behavior (e.g., eat more fruits and vegetables) or to cease acting in an unhealthful way (e.g., decrease binge drinking or smoking). For example, a theory may define principles to motivate someone to take medication correctly. It is also important to understand that theory tells us, by default, what factors are not important. Theory suggests what to do and what not to do. Table 5-2 identifies behavioral theories widely used in health promotion and potentially helpful when applied to infection prevention practices. This box's list is only illustrative not exhaustive.

**Table 5-2** Behavioral Science Theories Applicable to Infection Prevention Practice

Health Belief Model Social Cognitive Theory Transtheoretical Model Diffusion Theory Organizational Development Theory
In-depth presentation of each of these may be found in a number of texts. <sup>4</sup>

Healthcare personnel are seemingly hard-wired to address health education problems by giving people information. Telling, or giving people information, may take the form of one of a number of strategies including one-on-one exchanges with patients or healthcare personnel, group teaching, instructional materials, or electronic media. While giving information may have a role in bringing about change, it is rarely self-sufficient. Most IPs know this in their heart-of-hearts, but providing facts and giving information is often the only tool available. Yet, what might be a more effective approach?

For guidance on this, consider a health promotion planning model called PRECEDE/PROCEED.<sup>5</sup>This model shows that an educational diagnosis, which proposes that a target behavior, stated as a behavioral objective (see Table 5-1), may be changed by factors sorted into three categories: predisposing, enabling, and reinforcing. Predisposing factors are ones that will motivate people to make a change. Examples of predisposing factors include factual information, supportive attitudes and beliefs, and personal values. Although attitudes, beliefs, and values are difficult to change, the usual approach is to use educational and communication strategies to establish factual understanding and build attitudes that will help people to begin the change process. Theory provides guidance on what facts, attitudes, and beliefs are important (see Table 5-3).

Once people are motivated to begin the change process, enabling factors will capture their capacity to change. Capacity to change boils down to two issues: (1) do they have necessary skills and capability, and (2) do they have the necessary resources? For example, if the objective is for the healthcare personnel to use best practice gloving procedures, do they have appropriate gloves accessible when they need them and can they demonstrate the correct procedure for gloving? If the objective is for family or significant others visiting in the hospital to carry out best practice hand hygiene, do they have ready access to hand sanitizer and instruction? Training and coaching for skill development or by helping people obtain access to needed resources may improve enabling factors.

The last category of factors that supports change is called reinforcing factors because their impact occurs after the target behavior has been initiated and thereby determines whether it will continue into the future. Reinforcement may come from the responses and interactions of team members or supervisors to excellent performance or it may come from observing the example of a role model, or it may come from patients' visceral experience (e.g., soreness when beginning an exercise program) consequent to the behavior. Reinforcing factors can be managed to optimize behavioral compliance. An example applicable to infection prevention practices is implementing hand hygiene protocols that are based on the assumption that healthcare personnel want to comply with safe patient care practices. Thus, instead of a punitive response when noncompliance to hand hygiene is observed, the organization using reinforcing factors would respond with strategies to motivate proper hand hygiene techniques. For instance, a positive approach would be "I notice that you did not use hand hygiene prior to entering the patient's room and I know that you want the best care for the patient. What would help to ensure your compliance?" The organization may in this way identify that hand sanitizers are not located for easy accessibility or that the dispensers are not kept properly filled or that the healthcare personnel hands are full of supplies prior to entering the room. Implementing reinforcing factors to sustain practice is about know the "how" not just the "what" of hand hygiene compliance. An organization based on promoting culture of patient-centered care, rewarding positive behavior, and "drilling down" or analyzing the processes that lead to compliance is predicted to sustain excellent performance and patient outcomes.

**Table 5-3** An Example of Educational Diagnosis of a Behavioral Target

Eighty percent of outpatients will take their antibiotics correctly and for the entire course of the prescribed regimen.	
Predisposing factors	<ul style="list-style-type: none"> <li>• Patients will be able to summarize the benefits of taking antibiotics correctly, and the hazards of failing to take them correctly.</li> <li>• Patients will believe that their medication compliance will have a major impact on their recovery.</li> <li>• Nursing staff will know the consequences of exposure to common HAIs.</li> </ul>
Enabling factors	<ul style="list-style-type: none"> <li>• Patients have the skill and the confidence to take their antibiotics correctly.</li> <li>• Patients are able to fill the prescription or otherwise obtain their antibiotic medications.</li> <li>• Workers in clinical areas have easy access to sinks with antimicrobial soap and hot water.</li> </ul>

## Reinforcing factors

- Patients' medication taking will be encouraged and supported by spouse or other family members.
- Drug choice and dosage will be carefully monitored by the clinician to minimize side effects that will discourage compliance with the treatment plan.
- Clinical staff members are rewarded when observed washing hands coming out of a patient room.

This educational planning structure will make educational plans more comprehensive, increase the likelihood of addressing the range of critical issues determining success, and will identify logical points where behavioral theory can be helpful.

## REVIEW OF KEY BEHAVIORAL THEORIES

The oldest and most widely used behavioral theory is cognitive theory. Based on abundant research and experiential evidence, the cognitive approach is no longer tenable. In brief, cognitive theory prescribes that the way to change health-associated behavior is to give people appropriate factual information. Once they know, they will respond and change appropriately. A corollary is that unhealthy behavior is attributed to ignorance of factual information about the behavior and its consequences. To reiterate, possession of some facts (not all facts) may be important for behavior change, but almost never is enough to sustain long-term change unless other factors are addressed. Factors that sustain change are addressed in the following discussion of additional theories.

## THE HEALTH BELIEF MODEL

The health belief model (HBM) is the oldest theory specifically developed to understand and predict health-associated behavior. This is done by focusing on the attitudes and beliefs of individuals. The model was actually developed in response to the failure of a free tuberculosis (TB) health screening program in the 1950s. Since then, the HBM has been adapted to explore a variety of long- and short-term health behaviors, including sexual risk behaviors and the transmission of HIV/AIDS. Figure 5-1 illustrates the constructs of HBM.

HBM starts with the nature of beliefs in a target group regarding how serious a disease or health problem is and how likely they are to get the disease. The target group may consist of one person or a class of people, such as the employees of Hospital A. If the theory application is to a group of people, some assessment will be required to understand the prevailing beliefs. Whether the focus is on a single individual or a group, the intervention would try to narrow any gap between the actual seriousness and the beliefs that exist, and a gap between actual susceptibility or risk and existing beliefs about this, typically through education and communication methods and materials.

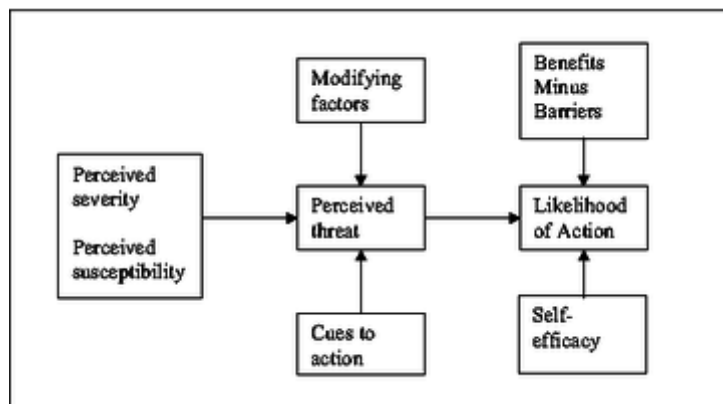
This becomes more complicated when the task is to persuade staff to take precautions so that patients do not succumb to an HAI. In this example, healthcare personnel will have some beliefs regarding their own susceptibility to infection in the context of their work, but their beliefs about the susceptibility of patients as a result of worker actions is one step removed. While research evidence does not shed light on this, it might be supposed that the double motivations of self-protection and patient protection should be stronger together than either standing alone.

### Figure 5-1.

The Health Belief Model.<sup>4</sup>

[View Image](#)





Modifying factors have limited practical value. However, these factors play a role in understanding the target group's learning needs and might have an impact on the design of interventions. Modifying factors include age group, gender, race and ethnic group, socioeconomic status, rural or urban residence, religious affiliation, and so forth.

Cues to action are communication messages or events that create heightened awareness regarding the need to respond in some way.

Examples include checkup reminder cards

received from the dentist, a caution or danger sign in the vicinity of some threat, and a serious and sudden life-threatening medical problem in a family member. The cue to action construct is similar to "teachable moment" in which a person is, by circumstances, most ready to listen and learn. Cues to action may have a very useful role in HAI prevention.

With respect to behaviors presented as solutions to a threatening health problem, people will weigh the plusses and minuses, the pros and cons, or, in HBM terminology, the benefits minus the barriers. In order for a behavior change to occur, the person must anticipate some gain: better health, social approval, financial savings, improved functioning, pleasure, and so forth. Gains are balanced against barriers: factors that make the change difficult or aversive consequences. Examples of barriers include participation made difficult by lack of childcare, ease of washing or disinfecting hands, expense of the kits that include all supplies for line insertion or maintenance, weight gain as a consequence of quitting smoking, and the perceived relatively high cost of eating healthy foods compared to junk food. The job of the IP or their designee is to make sure the benefits of relevant behavior are well known, to provide additional benefits (e.g., incentives), and to either eliminate barriers (e.g., provide gloves that do not easily tear) or to empower people to overcome the barriers (e.g., skills training).

The final construct in HBM is self-efficacy, which is the person's confidence in their ability to change and to sustain it long term. An example of a self-efficacy problem is the hopelessness seen in many dieters who have failed on a long list of diets; they begin to feel they cannot be successful. An example more pertinent to this discussion is the confidence among nursing staff that with all the stresses, time demands, and organizational chaos sometimes found in busy clinical units, they are really able to follow best practice hand hygiene 100 percent of the time. Promotion of self-efficacy comes by training and coaching in techniques, by providing supportive environments, and by periodic reinforcements.

It is clear that HBM shows potential for applications to various infection prevention behavioral challenges.<sup>7</sup>

**Figure 5-2.**

Reciprocal determinism from Social Cognitive Theory.<sup>4</sup>

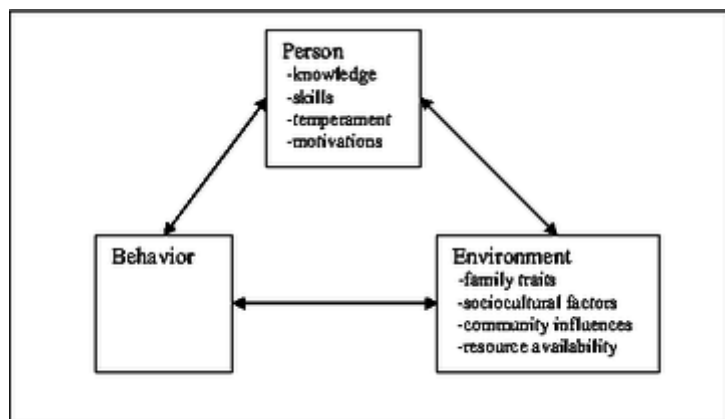
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## SOCIAL COGNITIVE THEORY

Social cognitive theory (SCT) is built around the interaction of the person (their knowledge, temperament, internal motives, skills), their behavior, and the environment (physical, social, organizational). The interaction of the three components is called reciprocal determinism (Figure 5-2). It



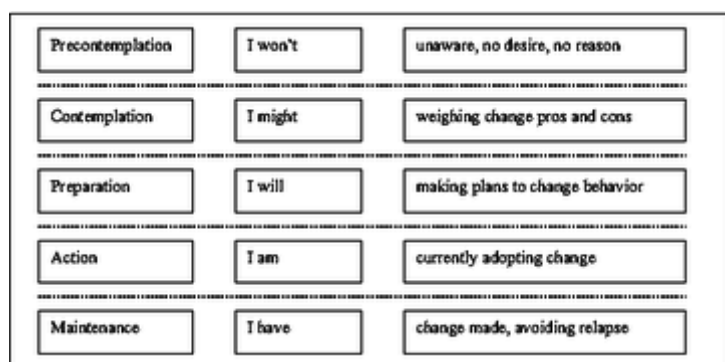


should be noted that the factors are linked, not in a one-way cycle, but in a way where each influences the other. In other words, while it is intuitive that environment will influence behavior, the model asserts that behavior also exerts an influence on the environment. For example, if you can get a critical mass of the staff of a clinical unit to comply with best practice hand hygiene, the social environment will be changed, providing a tipping point to impact those staff members lagging behind. Likewise, not only does the knowledge and attitudes impact behavior, but behavior change can

impact attitudes and beliefs. When state laws mandated adult use of car seat belts, many people were resistant. However, with extended experience in avoiding the consequences of disobeying the law, attitudes in the population have softened so that seat belt use has become a normal routine for most people, divorced from the threat of penalties.

So what are the implications of SCT in infection prevention? To begin with, a person's motivations, knowledge gaps, attitudes, and skill level must be addressed. This should be done in a multiphasic way, using varied methods in different places and times, over a term long enough to provide repeated reinforcement. It will be equally important to provide an environment supportive of change. This would include such things as peer support, prompts from patients to professionals, role modeling by leaders in the healthcare environment, compliance incentives, and organizational provisions to facilitate best practice behavior.

Some elements of HBM and SCT are compatible and complementary. Theory-based planning often will draw upon more than one theory to guide program development.



**Figure 5-3.**

Transtheoretical Model or Stage Theory

[View Image](#)



## TRANSTHEORETICAL MODEL OR STAGE THEORY

The principal concept behind stage theory is readiness. For any given health-associated behavior, people will have diverse orientations to change. Some will be unaware that a

particular change is a desirable option, whereas others have already completed the change but are at risk of reversing their progress or relapsing. The corollary to the recognition that people can be categorized by different levels of change readiness is that the methods applied to different levels of readiness will not be the same. For example, the infection prevention practices needed by a newly employed environmental services worker will be addressed in a way very different from providing refresher training to an experienced medical technologist. See Figure 5-3 for an illustration of transtheoretical model (TTM).

In the healthcare environment of a large institution, healthcare personnel will be at all levels of readiness to change as outlined by TTM. Perhaps the major group, the clinical professionals with



advanced degrees and training, will be in the maintenance stage of readiness with a history of applying infection prevention techniques. Yet, because of the lack of reinforcement or expectation of the organization, they are at risk for relapse to substandard practices. Stage theory provides the IP with concepts to tailor intervention approaches to the readiness-related learning needs of the various subgroups of the workforce.



**Figure 5-4.**

Stage theory applications to hand hygiene promotion.

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Having healthcare personnel complete brief questionnaires designed to assess perceptions and practices regarding a recommended action, such as hand hygiene, can be used to tailor the educational approach to meet the level of stage-based readiness. In addition, groups composed of different categories of healthcare personnel may be gathered into focus groups and interviewed to establish stage of readiness.

Educational strategies are adapted accordingly in addressing the needs of each of these groups. See Figure 5-4 for an illustration of strategies tailored to each level of the TTM.

## POSITIVE DEVIANCE

Positive deviance (PD) is a behavioral change approach that is based on the observation that in any community there exists individuals who have found uncommon practices and behaviors that enable them to achieve better results than their peers, despite the similarities of problems and available resources.<sup>8</sup>

This theory is grounded in the assumption that in every community there are untapped assets or resources. With the PD approach, sustainable behavioral and social change can be achieved through identification of solutions that already exist within a system. PD design consists of four steps: define, determine, discover, and design.<sup>8</sup>

This process has been successfully applied to infection prevention and other health-related problems.<sup>8,9,10</sup> The Pittsburgh VA hospital reduced the incidence of methicillin-resistant *Staphylococcus aureus* by more than 50 percent in a year and a half using PD.<sup>8</sup> Multiple hospitals, using PD, were able to significantly increase compliance with hand hygiene.<sup>8,10</sup> One of the key principles of PD is that the community must own the entire process. They must discover the uncommon successful behaviors and design ways to expand them into common practices that are used consistently monitoring their own progress.

## GENERAL CONCEPTS DRAWN FROM LEARNING AND BEHAVIORAL SCIENCE THEORIES<sup>8</sup>

In addition to the formal theories discussed, there are some general principles that should be considered when planning and implementing education and communication campaigns for patients, family members, or healthcare personnel. The following list of items provides some guidance to enhance program planning:

1. Include representatives of the target group into your planning. Not only does this promote ownership and responsibility, but it also can also provide insight into what might be more effective educational strategy.
2. If the target group has a lot of cultural diversity, it will be important to secure planning input from groups not in the cultural mainstream of the target group.
3. Repetition of concepts over time and with various instructional or communication tools will enhance learning.
4. As much as possible, employ active learning strategies as opposed to just relying on passive, one-way dissemination of information.
5. Encouragement and recognition of mastery enhance learning. Learners need to know that they understand, are meeting expectations, and have strengthened their competency.
6. Multisensory learning is more effective. In developing instructional and communication strategies, try to use visual, auditory, and, as appropriate, the senses of taste, touch, and smell. 7

Learners come with various levels of motivation, vocabulary and health literacy, existing habits and conceptions, and life experiences. Thus, an education program has to balance the efficiency of group instruction and communication against the limits of effectiveness that are a function of diverse learning needs in a group.

## ENVIRONMENTAL STRATEGIES

Experience has taught that education and communications must be supported by circumstances that facilitate action. For example, the success of seat belt education was greatly enhanced when seat belt use became mandatory. The success of youth tobacco education was increased by policies making cigarettes more expensive. Efforts to encourage employees to be more physically active can have greater impact, for example, by designing company stairways that are attractive and inviting.

## Conclusions

The lesson for IPs is that they should work with frontline staff to improve infection prevention practices through application of theory-based tools and processes to create sustainable change. They must also build in environmental strategies to make best practices easier to do. Examples of this include the number and placement of sinks and hand sanitizers, the easy availability of gloves and supplies needed for standard and transmission-based precautions, active involvement and encouragement by institutional leaders so that a safety-oriented climate is reinforced and sustained, use of soaps and sanitizers that are less irritating to skin, use of touchless faucets and towel dispensers, devices to monitor the frequency and duration of handwashing, and automated electronic prompts to remind staff to perform hand hygiene.

This combination of theory-based education, communications, and environmental approaches, including both physical and organizational circumstances, will greatly enhance the success of infection prevention processes reliant on behavior change.

## Future Trends

Infection prevention is at the interface between clinical care and public health. Clinical care tends to be oriented to one case at a time with an individual assessment-driven plan of care. On the other hand, public health assesses and intervenes with entire communities or target groups. To be most successful,

infection prevention must address clinical problems from a public health or systems approach. The supplemental reading at the end of the chapter reviews some of the published research on behavioral interventions in infection prevention. However, we are a long way from a finished evidence base. Much more research along those lines is waiting to be done. While numerous theories have been applied to behavior problems in infection prevention, there are many other theories that have not yet been tested in the infection prevention arena. Furthermore, theory researchers will undoubtedly demonstrate the validity of new theories with relevance in the future

In addition, the evidence on effective public and institutional policies that provide environmental supports for infection prevention is still in its infancy. Furthermore, there are new technological tools that provide solutions but also present new behavioral challenges. Finally, we must understand how infection prevention practice in tertiary care medical institutions translates to different settings of care and other community sites, such as athletic facilities and jails, where infections increasingly occur. This research agenda goes far out into the horizon and will occupy young researchers perhaps for the better part of their careers. Because of the very threatening rise in incidence of some of the most serious HAIs, these research questions must be supported and pursued.

## International Perspective

Infection prevention is a concern in healthcare in every corner of the globe. Because of the ease of international movement of people in the 21st century, there is the prospect of the homogenization of the microbial climate, requiring the same prevention efforts everywhere. We have not really seen this in full bloom, but instead tremendous diversity, even just within the United States, in the incidence of HAIs.

Nevertheless, infection prevention is required everywhere. It is fair to ask whether policies and procedures considered best practice in Western medical facilities are relevant and feasible in non-Western cultures, often with limited resources. It is also fair to ask whether behavioral theories, largely developed through research in Western populations, translates well to other cultures. Even in the United States, the recognized behavioral theories, such as those summarized in this chapter, do not necessarily explain and predict behavior perfectly. For example, we could use the HBM to design a campaign promoting human papillomavirus vaccination. However, some individuals and groups will have moral values related to use of the vaccine that will trump the HBM constructs. This risk becomes even more of a concern the further we are from psychosocial dynamics considered normal in mainstream Western culture. This does not mean that the theories are useless, but that it becomes even more critical to include members of program target groups into early planning so that you have "on-the-ground" perspectives of what might or might not be effective in a particular culture or geographic area.

The application of behavioral theories as tools to guide development of infection prevention and control programs is still fairly new, even in advanced nations and communities. This is even more the case in disadvantaged parts of the world. Whenever our understanding of best practice and the evidence base for interventions is deficient, which it clearly is in infection prevention, the critical need for rigorous evaluation is highlighted. We must determine what works and what does not work, disseminating our findings so that the knowledge base from intervention in the developed and the developing world are made available to all infection preventionists.

## Supplemental Resources

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## Healthcare Informatics and Information Technology

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### Abstract

*Reducing the risk and occurrence of infections is the result of an effective infection prevention and epidemiology program. Healthcare informatics and information technology provide a means by which evidence-based care bundles and infection prevention data can be effectively collected, stored, analyzed, and reported from documentation in the electronic healthcare record. The role of technology in infection prevention and control has increased due to regulatory requirements and the desire to secure patient health information. Healthcare informatics is a powerful tool to support infection preventionists to drive high compliance with evidence-based care bundles and in meeting requirements set forth for data availability and public reporting.*

### Key Concepts

- Information technology resources and processes are used to retrieve, distribute, and store packets of information to aid infection preventionists in effectively performing infection prevention-related tasks.
- Databases can speed and simplify the collection, management, and communication of information needed for infection prevention and treatment, surveillance, outbreak detection/investigation, education, and more.



- Information security requires safeguards to protect patient health information.
- Informatics is the process of applying computer technology to the scientific process. Informatics has improved the tools available to health, medical, and nursing professionals.
- Healthcare informatics and information technology foster quality improvement by enabling the use of evidence to monitor and improve processes and outcomes.
- Healthcare informatics and information technology support accurate, efficient extraction and upload of publicly reported infection data cases and data.
- Syndromic surveillance focuses on the detection of emerging infectious diseases and agents of bioterrorism.
- Mobile computing devices affect practice at the point of care by providing improved access to patient and diagnostic information, and have expanded to include mobile physicians via robotic design.
- Digital connectivity allows for greater clarity and accessibility, particularly with radiographic imaging, and promotes secure access such as digital certificates.
- Information technology will continue to advance toward increased capacity in smaller and more mobile devices as well as increased sharing of information across broader networks.

## Background

Information technology (IT) plays a pivotal role in the duties and responsibilities of infection preventionists (IPs). The IT structures of most healthcare institutions have undergone significant changes to meet the challenges set forth by complex data demands and health IT governmental regulations.

Healthcare and nursing informatics have transformed data collection from a manual data process to an automated electronic one. Yet, there are still opportunities to maximize the effectiveness of these tools. IPs spend a substantial amount of time utilizing systems for collecting, processing, storing, analyzing, reporting, and disseminating critical data. IPs are knowledge professionals, and therefore must be able to efficiently and effectively use the most current technologies available and embrace the systems used within their healthcare setting. This chapter reviews how IT affects and interacts with the practice of infection prevention and offers a primer on basic technologies and methods.

## Basic Principles

### HEALTHCARE INFORMATICS AND NURSING INFORMATICS

Informatics is the study of information processing with the purpose to translate knowledge into practice. Healthcare informatics is the science of using information technology to design, develop, apply, manage, organize, analyze, and optimize healthcare delivery with the goal to improve patient care processes.<sup>1</sup>

Tools include clinical guidelines, IT systems, and electronic devices. Foundational information technology terms and concepts are described in Appendix A (at the end of this chapter). Nursing informatics enhances the documentation accuracy and enables data analysis of nursing practice.<sup>2</sup>

### HIPAA, SECURITY, AND INTERNET SAFETY

Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) sets privacy standards and security standards for protected health information (PHI). Since its implementation, HIPAA has changed the way healthcare facilities collect and handle certain patient information, particularly to ensure the confidentiality of PHI at every stage. Changes in the law also have alerted the general public to the ways in which their personal health data are managed and disclosed to providers, healthcare entities, insurers, and data clearinghouses.

Healthcare providers must conduct a review of their data collection and entry practices and create policies that address:

- Data security
- Data privacy
- Data disclosure
- Notice of policies and procedures
- The expectation and practices of business associates
- Consent to disclose data
- Usage of research data

PHI is vulnerable to security breaches at several junctures. One is during the collection of data using portable, handheld, or wireless devices. Sensitive and confidential data may be vulnerable if such devices are lost, stolen, or left unattended. The use of passwords, encryption, and timed sign-off screens can make such devices more secure.

Security breaches also are possible in the infection prevention and control department during mandatory reporting of communicable diseases to local and state public health departments and the Centers for Disease Control and Prevention (CDC). When transmitting protected health information, IPs must ensure patients' privacy by using secure facsimile machines and facsimile cover sheets that instruct the recipient what to do if the information is reported in error or is incomplete.

The security of email and Internet communications is usually regulated at the facility or corporate level (i.e., by the IT department). However, IPs must be vigilant against accidentally including sensitive information in material that is copied or forwarded to multiple recipients or electronic lists. Highly sensitive data can be protected with the use of encryption and verification tools such as digital signatures, passwords, key codes, or digital certificates.

## REGULATORY-BASED SURVEILLANCE

### *THE ROLE OF PUBLIC HEALTHCARE-ASSOCIATED INFECTION REPORTING AND PREVENTION*

The prevention of healthcare-associated infections (HAIs) is now a very public issue in response to evidence that HAIs are largely preventable and that HAI deaths rank among the highest causes of deaths in the United States. In 2009, the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan)* was developed by the U.S. Department of Health and Human Services (HHS).<sup>3</sup> Initially, the reduction of HAI rates targeted acute care hospitals; however, the scope of the action plan has expanded over past years to include additional healthcare settings in the nonacute and ambulatory setting. Acute care targets include: central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), surgical site infections (SSIs),

methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (*C. difficile*), and influenza vaccination among healthcare personnel.<sup>3</sup>

In response to the American Recovery and Reinvestment Act of 2009 (P.L. 111-5), all states developed HAI Action Plans consistent with the National HAI Action Plan. In addition, since 2003, 30 states have enacted HAI reporting laws.<sup>4</sup>

In compliance with the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program added HAI measures effective with the federal fiscal year 2013 payment determination period. Hospitals receiving Medicare reimbursement must enroll, complete National Healthcare Safety Network (NHSN) training, and submit HAI data to NHSN in order to comply. Nonparticipation or noncompliance will result in a reduction to the hospital's annual market basket update, with the percentage of the reduction determined each year by CMS.<sup>5</sup> Annually, CMS performs validation of HAI measures on randomly selected and targeted participating hospitals.<sup>6</sup> Hospitals chosen for validation are required to use validation templates to submit patient lists from specified locations that include specified pathogens (from cultures or nucleic acid amplification testing) as defined by CMS rules for validation of HAI reporting measures in NHSN—for example, positive urine and blood cultures for validation of CLABSI and CAUTI reporting in NHSN.

HAI reporting measures are published by CMS on the Hospital Compare website (<http://www.medicare.gov/hospitalcompare/search.html>) to allow consumers to make informed decisions regarding their healthcare choices.

### *NHSN REPORTING AND CMS DATA VALIDATION*

The CDC collects HAI measure data via the NHSN application and uses these datasets to track and trend national HAI data. This secure application is used by U.S. hospitals for voluntary reporting of internal HAI tracking as well as to meet public reporting requirements for states and the CMS IQR program.

#### *NHSN Reporting*

There are four methods that can be utilized to enter reporting data into NHSN: manual entry (direct entry of reporting data into NHSN reporting modules); electronic imports via ASCII comma delimited text files, also known as comma separated value (CSV); electronic imports via clinical document architecture (CDA); and automated send NwHIN Direct, also known as batch submission, via CDA.

It is important to note that electronic imports (CSV and CDA files) and automated send NwHIN Direct can only be used to upload reporting datasets that NHSN has made acceptable to the NHSN application (see the CDC National Healthcare Safety Network website for more information).

#### *Manual Entry*

All HAI measure data can be manually entered into NHSN by directly entering reporting elements into each field of the applicable NHSN reporting module. This manual methodology allows all facilities to have a means of complying with public reporting compliance. Traditionally, data elements for manual entry are sourced by the IP during surveillance. The IP may access required reporting data via manual review of paper and electronic medical records and/or retrieve needed reporting data for analysis via reports in the electronic health record (EHR) or other external databases. Due to increasing HAI

reporting requirements, many hospitals are utilizing electronic reporting options to decrease the clerical burden of public reporting.

### *Electronic Methods*

NHSN is committed to providing electronic reporting options that may be used to streamline reporting into the NHSN application. Facilities may choose to leverage technology to capture reporting elements from their EHR or other external databases. The method chosen is often driven by the accessibility of needed data elements and the resources available at the organization, such as the technological skills to build or the capital to develop or purchase software for this purpose.

### *Sourcing Data for Electronic Reporting*

The extraction of clinical data from the EHR requires, at minimum, a semistructured EHR that has standardized entry of clinical data in order to allow for data to be located for extraction.<sup>7</sup>Laboratory, medication administration, diagnostic data, and admission, discharge, and transfer (ADT) data may be sourced from different electronic sources housing medical information. Clinical data elements such as lines and device insertion/discontinuation and vital signs can only become useful for electronic data capture when documentation entry is standardized to a defined location in the EHR.<sup>7</sup>

### *ASCII Comma Delimited Files*

Electronic importing options available in NHSN include the importation of ASCII comma delimited text files, also known as CSV, which are used to package reporting data in the required order and format defined by NHSN. Facilities may have an opportunity to capture all or a portion of the required reporting elements from the EHR into a CSV file.<sup>8,9</sup>

The electronic data captured in the CSV file can be viewed by the IP in a spreadsheet format which gives the IP the opportunity to validate and revise data fields as needed, as well as add any missing data elements that could not be extracted from the EHR. This electronic reporting method is the least complex NHSN electronic reporting option but may only be used to import those reporting measures that have been provided as an option in the NHSN application. Reporting data housed in CSV files need to be manually imported into a facility's NHSN reporting application.

### *Clinical Document Architecture*

CDA file development is complex and typically implemented through vendor software. HHS published a set of Health Level 7 (HL7) standards in the Final Rule of Health Information Technology.<sup>10</sup>HL7 codes are standardized message codes that allow information to be packaged and communicated from one system to another. Because HL7 codes are used universally from one EHR system to the next, data packaged within HL7 codes can be captured and used for creating CDA files. For example, ADT, microbiology and lab reports, radiology reports, dictated reports, and pharmacy data are typically packaged in HL7s.

CDA files allow for more robust NHSN electronic reporting options than CSV files, including event reporting (SSI, CLABSI, CAUTI, and laboratory identified event) and reporting of device aggregates for summary data. Infection prevention surveillance systems are designed to capture the needed datasets for reporting from the infection classification documentation entered in the system by the IP. NHSN reporting data can then be exported into a CDA file that meets NHSN CDA specifications. During this process most systems will also analyze the data being exported to the CDA file and alert the IP to any

errors that would preclude acceptance to NHSN. CDA files are imported manually by the facility into the NHSN application.

#### *Automated Send NwHIN Direct*

Automated Send NwHIN Direct, also known as batch submission, automates submission of reporting data into NHSN. CDA files containing the reporting data from one or more facilities are compressed, pushed to NHSN, and incorporated into a facility's NHSN reporting application. The direct messages generated by the source, typically an infection prevention surveillance system, package the reporting data to conform to direct-prescribed message structure.<sup>6</sup>

#### *Reporting Integrity*

Electronic reporting requires validation of data by the facility prior to import or automated submission to NHSN to ensure that the information provided is accurate and complete. In addition, submitters are expected to review data imported to NHSN to validate the submission.<sup>11</sup>

#### *Additional Reporting Steps*

Facilities that submit reporting data electronically to NHSN will still be required to access NHSN and manually perform required reporting steps to complete NHSN reporting, such as monthly reporting plans, annual surveys, and maintaining reporting locations mapping. In addition, manual entry of some reporting elements may be required if available as an option for electronic reporting in NHSN.

#### *CMS Data Validation*

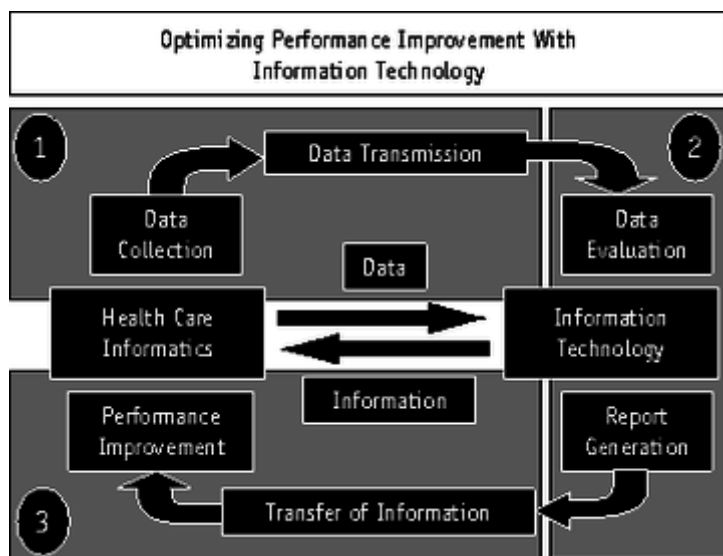
Hospitals selected for HAI measures validation are required to use CMS validation templates to submit patient lists from specified locations that include specified pathogens (from cultures or nucleic acid amplification testing) as defined by CMS rules for validation of HAI reporting measures in NHSN—for example, positive urine and blood cultures for validation of CLABSI and CAUTI reporting in NHSN.<sup>12</sup>

Specified criteria for identification of qualifying labs must be applied and the data must be reported in the format and order defined within the validation templates. Hospitals may choose to leverage electronic technology to identify cases and extract required reporting elements, in the format and order required, from medical information sources. Data may be captured in an excel file or CSV file, reviewed for accuracy and completeness, and then transferred (i.e., copied and pasted) onto the required CMS validation template for submission.

## QUALITY IMPROVEMENT AND INFORMATION TECHNOLOGY

In healthcare, the focus is on patient care and patient safety. IT can foster creative methods for monitoring and improving quality, performance, and infection prevention, as noted in Figure 6-1. For instance, The Joint Commission defines the seventh national patient safety goal as reducing the risk for HAIs, which is directly related to infection prevention. This goal is evidenced by two components: (1) compliance with the CDC's hand hygiene guidelines, and (2) managing all cases of HAI that result in unanticipated death or major permanent loss of function as sentinel events. For many healthcare providers, meeting this goal requires computerized monitoring of patient outcomes, sources of infection, and staff compliance with hand hygiene training and practice. The Joint Commission set forth those safety initiatives; CMS set forth the ninth scope of work. The ninth scope of work stipulates the nonpayment of certain HAIs (e.g., urinary tract infections and bloodstream infections). As this process

continues to emerge, the need for computerized data to facilitate accurate, efficient data submission for public reporting of infections is now more evident than ever before.



**Figure 6-1.**

Optimizing performance improvement with information.

[View Image](#)



## EMERGING INFECTIOUS DISEASES AND SYNDROMIC SURVEILLANCE PROCESSES

As technology changes, so does the role of the IP. Technology is necessary for the task of syndromic surveillance, a continuing challenge for infection prevention departments, agencies, and centers in the face of a threat of bioterrorism and national or global disease outbreaks or epidemics. In the wake of threats

such as anthrax, severe acute respiratory syndrome (SARS), monkeypox, avian and swine influenza, and Middle East respiratory syndrome coronavirus, IPs must implement bioterrorism preparedness initiatives and conduct syndromic surveillance to identify and curtail the spread of disease in a population. Emergency preparedness efforts must focus on handling influxes of patients with confirmed or suspected exposure to a novel or rapidly transmissible disease. Advanced knowledge of a situation such as this is paramount to facilitate preparation efforts; thus, surveillance should encompass a wide variety of healthcare data. Syndromic surveillance is designed to accomplish this task. Syndromic surveillance is conducted on a very large scale, combining data from multiple sites or geographical areas. Surveillance of this magnitude requires highly technical, adaptive, and powerful systems that can import data from multiple sources and use a form of data mining to generate alerts when unusual clusters of syndromes are identified.<sup>13</sup>

The state of Florida established the ESSENCE system for emergency departments (ED) and urgent care centers in 2007.<sup>14</sup> As of 2011, approximately 85 percent of emergency visits are monitored by ESSENCE via daily electronic transmission of an electronic record in a standard format for every ED visit in participating hospitals. Records are electronically extracted from the healthcare information system, requiring no manual entries, including age, sex, zip code, date, time, and chief complaint. ESSENCE searches for key words in the chief complaint and assigns each record to one or more syndromes. Discharge diagnoses are sent with follow-up record transmissions.

Healthcare informatics can be leveraged to perform syndromic surveillance performed at the local facility level to detect sudden spikes with inpatient admissions. An example of screening patients for acute respiratory infections is shown in Figure 6-2.

## MEANINGFUL USE AND TECHNOLOGY

A report first published in 2001 by the Committee on the Quality of Health Care in America (a committee within the Institute of Medicine) specifically recommended the use of IT to improve access to information and support evidence-based decision making.<sup>15</sup> It recommended a national commitment to building an information infrastructure to support healthcare delivery, consumer health, quality



measurement and improvement, public accountability, clinical and health services research, and clinical education.

Many healthcare facilities use data networks to consolidate clinical laboratories, share patient health data among providers, allow physicians to review and sign a multitude of orders for patient care, facilitate communication among consulting physicians, and more. Implementation of risk management strategies helps maximize protection of patient health information. The Patient Protection and Affordable Care Act (PPACA) is a federal statute signed into law in 2010 preserving patient privacy and confidentiality and has impacted healthcare and nursing informatics.

On February 17, 2009, the American Recovery and Reinvestment Act (ARRA) was signed into law. As part of ARRA, the Health Information Technology for Economic and Clinical Health Act (HITECH) established incentives for the "meaningful use" of certified EHR technology. Over \$27 billion in incentive payments have been made available to help promote and encourage the use of health information technology (HIT) in a "meaningful manner." Meaningful use Stage 1 incentives ended in 2012 and Stage 2 incentives began in 2013.<sup>16 17</sup> The new HITECH environment has been transformative, enabling healthcare professionals to have access to electronic data, feedback on performance measured by evidence, and continuous monitoring at the point of care.

The screenshot shows a digital form titled "Sample electronic screening for acute respiratory infections at the point of patient entry". The form includes the following fields and questions:

- Is Patient Present? (Dropdown menu)
- Reason- (Text input field)
- Is patient currently experiencing any of following in last 7 days:
  - Fever greater than 100.4? (37.8 C) (not related to allergy or CDP)
  - Cough?
  - Persistent Cough greater than 3 weeks?
  - Cough with blood produced?
  - Sore Throat?
  - Night sweats?
  - Unexplained weight loss?
  - Fatigue?
  - Body Aches?
  - Rash?
  - Nasal Congestion (not related to allergies or sinus infections)?

**Figure 6-2.**

Sample electronic screening for acute respiratory infections at the point of patient entry (courtesy of Julia A. Mood)

[View Image](#)



HITECH incentives are only available to those eligible professionals (EPs) and hospitals that successfully implement, utilize, and attest to using EHRs as defined by a series of final rules developed specifically for each stage of the

program. It is important to note that attestation for meaningful use is "all or nothing" in terms of approach. Therefore, hospitals must meet and achieve *all* of the requirements and thresholds as defined in each stage in order to attest and receive the HITECH incentive payments.

Starting in 2015, CMS will begin to apply payment adjustments (i.e., penalties) to providers who do not participate in the EHR incentive program.<sup>16</sup> The payment adjustment is applied annually if the provider does not meet meaningful use requirements, with a maximum adjustment after 2018.

Meaningful use strives to address national health policy goals. These five goals are to improve quality, safety, and efficiency and reduce health disparities; engage patients and their families in their care; improve care coordination; improve population and public health; and ensure adequate privacy and security protections for personal health information

## HOW IS "MEANINGFUL USE" DEFINED?

Meaningful use is defined by meeting three stages of progressively more rigorous requirements established by CMS. Each stage includes specific requirements for core and menu set objectives, measures, and EHR certification standards that must also be achieved.

Essentially, EHRs are digital versions of patients' paper charts and provide real-time, patient-centered records. They make information available instantly, "whenever and wherever it is needed" to authorized

healthcare professionals. EHRs bring together, in one place, everything about a patient's health. The regulatory requirements of meaningful use have helped to provide a powerful framework for the healthcare industry and have accelerated the transition from paper-based documentation to EHRs.

## THREE STAGES OF MEANINGFUL USE

Stage 1 requires hospitals to implement and use certified EHR technology to demonstrate 14 core criteria functions, and to select and fulfill 5 out of 10 criteria from a "menu" of possible options and 15 clinical quality measures. This stage of the program formed the framework for data capture and sharing. The last year to begin participation in the EHR incentive program (i.e., start Stage 1) is 2014. All providers must participate and achieve meaningful use under the Stage 1 criteria prior to transitioning to Stage 2.

The Stage 2 Final Rule was published on September 4, 2012, and seeks to build on the Stage 1 foundation while advancing clinical processes, interoperability, and increasing patient engagement. Shared access to electronic health information between providers and patients can foster collaboration in managing and treating chronic health conditions such as asthma, diabetes, and obesity. Interoperability leads to improved care coordination between providers and care teams, especially during transitions of care, thus reducing the fragmentation of patient care.

Although the specific requirements and final measures for the third phase of meaningful use have not been published, Stage 3 will focus on improving outcomes and overall population health.

## WHAT ARE THE MEANINGFUL USE CORE OBJECTIVES?

Meaningful use core objectives can be leveraged to support surveillance activities. Healthcare facilities can select meaningful use objectives for a best fit. Core objectives include:

- Computerized physician order entry (CPOE) to standardize evidence-based care (e.g., influenza immunizations, ventilator care bundles)
- Patient demographics
- Vital signs
- Clinical lab test results are incorporated into certified electronic health record technology (CEHRT)
- Patient lists of patients with a specific condition (e.g., MRSA)
- Immunization registries data submission
- Electronic submission of lab results to public health agencies (note: public health agencies often lag behind with technology that can accept results)
- Syndromic surveillance data submission to public health agencies (e.g., ED diagnoses to detect sudden increased volumes due to a specific clinical syndrome such as diarrhea)

## TRANSFORMING HEALTHCARE

Meaningful use presents healthcare providers with an opportunity to strategically lead, improve, and transform the quality of care and healthcare delivery to patients. Research and the advancement of HIT outcomes offer the ability to improve access to comprehensive health data. Patient-centered health information exchange (HIE) has important implications for the future of infection prevention in terms of the ability to spot trends and improve infection surveillance tools.

## Trends in Technology

Telehealth is used as a means to reach a wide variety of audiences in various locations. Telehealth is the use of telecommunications technologies to deliver health-related services and information that support patient care, administrative activities, and health education.<sup>18</sup> The convenience of telehealth supports improved access to care and reduction of related expenses.

Mobile technology continues to provide rapid and portable access to resources with the introduction of new devices designed for easy retrieval of information. Smart phones are used commonly to access the Internet and transmit information using a 4G or fourth-generation network. Mobile technology can be recognized in several different ways. Knowledge-based systems are defined by the use of mobile computing devices to access drug information databases, medical reference manuals, and other educational materials. Legacy systems are characterized by point solutions that solve a specific business problem or conduct a specific process and are tightly integrated with back-office clinical systems. These systems include patient management, tracking, laboratory entry, and viewing. Enterprise systems encompass a step forward, incorporating mobile devices into new applications including electronic medical records, CPOE, and clinical decision support.

Most mobility tools used in healthcare are supported by wireless networks, mainly wireless local area networks (WLANs). Most organizations that use notebooks and laptops as their primary network access platform do so with WLAN. Wireless technology can benefit patient care in several ways. The two-way transfer of data process allows for the creation, updating, and deletion of patient records from off-site locations. Mobile devices improve the speed of transmission, security, and dependability. Mobile devices are very convenient, affording users complete access to most desktop applications literally in the palms of their hands.

The information from most handheld devices can be sent or transferred to desktop or network computers through cable or wireless connections. Synchronization also transfers information and updates from the larger system to the handheld version. Infrared capabilities allow some handheld devices to "beam" or exchange information with other similar devices as long as the devices are in close proximity. Beaming also facilitates the transfer of information from appropriately equipped handhelds to local or network printers. The addition of digital photography capabilities to handheld devices has transformed many handheld devices into diagnostic tools. Other handhelds also incorporate cellular telephones, global positioning system (GPS) devices, voice recorders, MP3 players, and wireless Internet access.

Additional trends include interconnected patient monitoring systems that facilitate accurate and timely data transfer from devices (like vital signs monitors) directly into the EHR and personal computer tablets in place of fixed workstations.

#### *INTRANET FACILITATES NETWORKING AND COMMUNICATION*

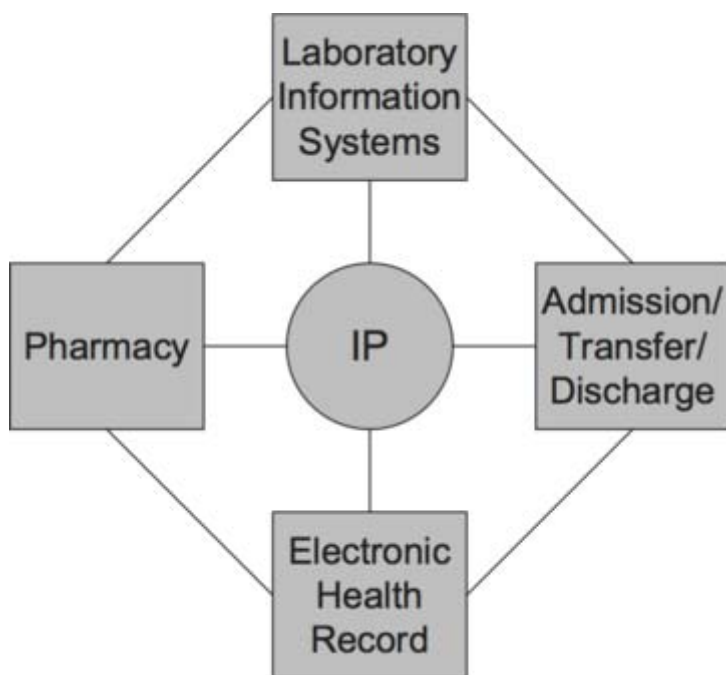
Organizations continue to make progress in technology in that an increasing amount of information is computerized, including paystubs, benefit statements, and newsletters. Intranets, or internal Internet systems, are widely used and have increased in popularity; they typically serve as a portal for resources and tools. Policies and procedures as well as success stories and data outcomes are posted for ease of accessibility and retrieval. A blog, or Web log, is a Web page that serves as a publicly accessible personal journal for individuals or, in infection prevention, professionals to dialogue. Blog sites serve as a means for dissemination of information on a more personal note. Blogs and shared workspaces on intranets provide communication spaces to meet the demand of the population that requires infection prevention data. This also facilitates a "green initiative" in that paper documents are minimized.

## Healthcare Informatics and Information Technology for the Prevention of Infection

Informatics is the application of computer science and information science to the management and processing of data, information, and knowledge. Informatics has become an area of specialization and is integrated into many different healthcare realms.

The application of IT and informatics in preventing infections is evidenced by the use in surveillance for HAIs. Interface engines are designed to retrieve pertinent clinical data from the laboratory information systems (LISs), enabling the IP to obtain real-time information necessary for intervention. Computerized ordering systems help standardize order sets and improve patient safety by building in error-checking mechanisms. Decision support tools, artificial intelligence, and evidence-based practices facilitate the automation of bundled protocols, such as the ventilator-associated pneumonia bundle. In this example, when a patient is ventilated an order is generated to implement the bundle, complete with compliance monitoring. The clinical information system (CIS) can be used as an education tool for the IP to communicate pertinent information to clinical personnel during patient care documentation activities by using pop-up boxes, thereby improving the dissemination of infection prevention knowledge.<sup>19</sup> Blogs, as mentioned earlier, have found their way into the IP's toolbox, providing an informal messaging system. Sophisticated surveillance systems act as liaisons between various information systems pulling data from pharmacy, laboratory, and admission/transfer/discharge records and applying algorithms to identify potential infections and alerting the IP, as illustrated by Figure 6-3. Computer algorithms have been used to identify blood culture results that could be excluded as sources of a CLABSI, effectively offering an automated surveillance method for CLABSIs.<sup>20</sup> Informatics has been used to track employee influenza vaccination rates via a network intranet system as part of an effort to effectively capture immunization data.<sup>21</sup>

Healthcare informatics has been broadened to include the cognitive, information processing, and communication tasks involved in medical practice, education, and research. Clinical specialists with training in informatics are now being called on to design and develop systems for use in acute and long-term healthcare settings.



**Figure 6-3.**

Linking information to the infecti

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### ELECTRONIC VENDOR SOFTWARE SOLUTIONS

The work of the IP includes those activities necessary to prevent and control HAIs. This includes surveillance, which is key to identifying increases in infection rates, recognizing adverse trends, and assessing performance improvement initiatives. These activities require an increasing amount of clerical tasks, including manual review of microbiology reports, which divert IPs from clinical, education, and consultative tasks. Manual surveillance has been estimated to consume up to 45 percent of an IP's time.<sup>22</sup>

With continued advancement in information technology and electronic medical records, new tools are available for the automation of data collection and surveillance.<sup>23</sup> While these new systems have the potential to reduce the clerical time required for surveillance activities,<sup>24</sup> they must be carefully selected to ensure compatibility with existing electronic health record systems in place at a facility, provide the necessary features to meet the internal goals of the organization, and be effectively incorporated into the IP workflow to optimize infection prevention resources.<sup>25</sup> These systems can be complex, drawing from various databases and systems, and require a minimum of a semistructured EHR to allow the system to reliably capture the necessary data for infection prevention surveillance. The IP workflow should be supported and easily merged with the system to ease IP adoption of the system and enhance the clinical and administrative duties of IPs in order to maximize their potential to facilitate data review, promote rapid detection of outbreaks, and improve infection prevention processes.<sup>26</sup>

### *THE BUSINESS CASE AND VENDOR SELECTION PROCESSES*

A structured EHR system and standardized documentation streamline the integration and mapping of source data into the vendor system. Available IP software systems should be evaluated for the ability to present clinical information, by patient, from a single or multiple healthcare record platforms, including EHR nursing and physician documentation, laboratory and microbiology results, radiology reports, admit/discharge/transfer status, surgical procedures, device information, and pharmacy or surgical medication administration. It is equally important to understand how this electronic clinical information is stored in the healthcare system's existing EHR.

Basic steps for selecting an electronic vendor solution include:

1. Create business case and obtain approval
2. Make a formal request for proposal
3. Schedule vendor product demonstrations
4. Identify healthcare system subject matter experts in clinical and integration, architecture, and security (IT&S)
5. Make sample electronic data available on DVD beforehand to use during demos
6. Create a scoring template for functionality and weighting (e.g., clinical 60 percent, and technical 40 percent)
7. Obtain consensus and ranking of vendors
8. Update business case and obtain funding
9. Finalize vendor of choice with contract
10. Initiate implementation planning
  - a. Configuration of alerts, reports, notifiable diseases
  - b. IT&S server, programming, certification
  - c. Test environment data feed; validation and testing
  - d. Production programming
  - e. Go live

## DESIGN AND IMPLEMENTATION FOR WORKFLOW AND EFFICACY

Organizations may want to invest time and resources into planning and designing the implementation of IP software prior to deploying. A well-planned deployment can avoid unexpected problems and lay a sound foundation for leveraging the technology to address the challenges facing IPs and aligning and standardizing the IP workflow with the system to promote efficiency and continuity. The hypothesis is that a planned implementation will increase the likelihood that infection prevention software would help



optimize IP resources, shift IP tasks from clerical to clinical, and streamline submissions for public reporting. Table 6-1 displays the shift in IP tasks from one experience with a planned implementation based on time studies before and after the implementation.

**Table 6-1** Shifts in IP Workflow from Clerical to Clinical with Planned Implementation of Electronic Surveillance\*

IP Workflow Categories	Percent of Work Time		Difference
	Pre-implementation	Post-implementation	
<b>Surveillance</b>	21%	26%	+5
<b>Public Reporting</b>	7%	5%	-2
<b>Clinical:</b> Education/preventative interventions	13%	23%	+10
<b>Clerical:</b> Report preparation	18%	11%	-7
<b>Rounding:</b> Device reports; isolation rounds; hand hygiene	13%	13%	0
<b>Consulting:</b> Employee/patient exposures; patient isolation status/cohorting (bed board); outbreak investigations; reconciliation of isolation status	10%	7%	-3
<b>Other:</b> Alerts, daily reports	18%	16%	-2

\*Bienvenu SB, Moody J, Hickok J, et al. Optimizing infection prevention resources through standardization of workflow integrated with infection prevention software. *Am J Infect Control* 2013;41(6, Supplement):S21–S22.

Once the software selection is made, it can be leveraged as a framework for the standardization of the IP workflow. The design of the workflow should target the major activities of the IP work day as defined by Grota et al., including (1) managing surveillance through the collection and creation of reports, case review and analysis, and interpretation of data; (2) public reporting to both national and state agencies; (3) daily isolation issues; (4) consultation and teaching; and (5) other activities including policy development, product evaluation, and emergency preparedness.<sup>27</sup> The workflow design should integrate with the software to standardize IP work processes, document cases, and report outputs. The workflow and the software should work in concert to follow a logical workflow progression to maximize continuity in surveillance, reporting, and analysis.

System templates can be designed to support the IP workflow and ensure that the IP reliably accesses the same work datasets defined for each of the major work activities—for example, current alerts for notifiable diseases, flags for isolation precautions, positive microbiology or other laboratory findings for surveillance, and infection classification. Templates can increase consistency and decrease the potential for user errors, thus improving the quality and ease of surveillance. In addition, templates should address all work datasets necessary for national and state reporting, including urgent notifiable communicable diseases and early identification of HAIs and multidrug-resistant organisms.

System-specific inputs for documentation of NHSN-defined infection classifications, including CLABSI, CAUTI, and SSI, should be predefined to facilitate the consistent selection of required documentation elements that are needed to produce the intended infection report outputs. Understanding the selected software's design and report output drivers is essential to defining the needed documentation elements



to consistently capture each infection type. This approach is recommended in addition to the use of the system data scrubbing technology that runs infection classifications through algorithms to determine if all criteria are met for NHSN reporting. Consideration may also be given to leveraging the system to document nonqualifying NHSN reportable cases (such as community-associated infections and secondary infections) to facilitate more robust report outputs and audit trail documentation that can be used for validation of case classification, especially in light of CMS HAI validation.

The organization's surveillance strategies should be reevaluated during the preimplementation period. Consideration should be given to leveraging the efficiencies of an electronic surveillance methodology to expand surveillance beyond targeted areas identified in the annual risk assessment. Areas of expanded surveillance may include whole house surveillance (all patient units), defining alerts for organisms of interest based on local epidemiology, syndromic surveillance (such as sepsis), and utilization of system functionality to support infection prevention rounding. Identified surveillance strategies should be incorporated into the custom standardized workflow, system design, and training.

System outputs should be predefined to facilitate on-demand infection reports and dashboards to meet the organization's needs. Optimally, system reports and dashboards will be developed to replace current reporting methods that are often manual or require assimilation of data from various sources. Careful planning and collaboration with key stakeholders is needed to transition to system reports by identifying needed reports, developing an interim process to report legacy data while new data is accumulating within the system, and considering new report opportunities afforded by the system, such as "Days Since Last Infection" reports.

System training should be developed to reinforce the workflow design conceptualized by the organization. This can be accomplished by introducing software modules in concert with daily IP workflow to ease the transition from manual to electronic processes. The training should include the basics of the software as well as the organization's customization of the software and system templates to ensure accuracy and consistency for reporting and surveillance. Optimally, training will be conducted with a small student to teacher ratio, such as 10:2, and presented in person by the vendor trainer and a trainer from the organization that is familiar with the customization of the workflow and the system usage. Training will typically be conducted in the facility's live infection prevention surveillance system environment and include classroom work as well as applied learning sessions via coaching calls or WebEx sessions to support the end user during the first 2 to 3 months. This approach will assist the student end user in gaining confidence in their abilities and reinforce appropriate utilization of the system and customized workflow. In addition to vendor system training guides, the development of an organizational customization guide is recommended to ensure continuity of practice and system utilization.

By anticipating the essentials of implementation, an organization can develop and design customized standards that will set the stage for successful deployment and adoption of an electronic infection prevention surveillance system. This, in turn, will provide opportunity to optimize IP resources, improve data integrity for surveillance and reporting, and lay a foundation to improve patient outcomes and reductions in HAIs.

## Conclusions

Healthcare IT supports improvements in the efficacy of care delivery and patient safety as well as the expansion of surveillance and epidemiologic population studies.

The trend in healthcare IT is for devices to get smaller and for their capabilities and capacity to increase. New devices offer faster and more integrated features related to functionality, security, and privacy. Wireless technology continues to grow and expand, allowing continual and uninterrupted access to online data, tools, and resources. Data and applications interconnect across multiple software platforms. Patient care devices log and track increasing amounts of data.

For the IP, these trends mean broader and more readily available access to information, analysis, and communication. Information technology is a powerful component of a comprehensive infection prevention program. The benefits of healthcare IT include optimizing evidence-based care practices, identifying patients at highest risk of infection in order to implement strategic interventions, and improving regulatory reporting. IPs should embrace and adopt IT in order to enhance the effectiveness and efficiency of infection prevention and control programs and to reallocate infection prevention resources from clerical duties to clinical leadership activities.

## Future Trends

Healthcare informatics and the field of infection prevention will continue to be positively impacted through development of technology advances. The portability, interconnectivity, availability, and breadth of information will guide decision making in patient care, patient safety, research, and infection prevention strategies.

## International Perspective

Healthcare and surveillance IT has effectively removed barriers between countries around the globe. The effective use of shared data was demonstrated during the 2002 to 2003 SARS epidemic and continues with the dissemination of data about novel strains of avian and swine influenza viruses. The World Health Organization (WHO) provides current data via the use of their website and reaches a broad international audience that supports dissemination of critical epidemiological data trends. WHONET software is an example of an internationally based program. This Windows-based database software was developed for the management of microbiology laboratory data and the analysis of antimicrobial susceptibility test results. WHONET can be obtained via the WHO website.<sup>28</sup>

The global expansion of mobile devices, software applications, and Web-based technology tools promote the ability to perform surveillance activities in resource limited settings.

## Supplemental Resources

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Gundlapalli AV, Olson J, Smith SP, et al. Hospital electronic medical record-based public health surveillance deployed during the 2002 Winter Olympic Games. *Am J Infect Control*2007;35:163–171.

Murphy DM. From expert data collectors to interventionists: changing the focus for infection control professionals. *Am J Infect Control*2002;30:120–132.

### Organization Websites

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American Medical Informatics Association. Available at: <http://www.amia.org>.

American Nursing Informatics Association. Available at: <http://www.ania.org>.

Certification Commission for Healthcare Information Technology. Available at: <http://www.cchit.org>

Healthcare Information and Management Systems Society. Available at: <http://www.himss.org>.

Information Technology Association of Canada. Available at: <http://www.itac.ca>.

International Medical Informatics Association. Available at: <http://www.imia.org>

## Appendix A

### Basic Principles

What is information technology? *Information* is defined as the communication or reception of knowledge or intelligence. *Technology* is defined as the practical application of knowledge. *Information technology* is how the data we gather is handled, with data being the factual information. It is the use of modern technology to create, store, exchange, and manipulate information and use it as a basis for reasoning, discussion, or calculation. Information technology is defined as "the study, design, development, implementation, support or management of computer-based information systems, particularly software applications and computer hardware."<sup>1</sup> Information technology deals with the use of electronic computers and computer software to convert, store, protect, process, transmit, and securely retrieve information.

Changes or "upgrades" in information technology occur on an almost daily basis. Information technology continues to progress at a rapid pace. Data punch cards of the 1960s and 1970s have been replaced by microprocessors, tablet computers, personal digital assistants, wireless networks, and streamlined Internet. Keeping up with such changes requires us to continually learn new ways to speak, work, and interact. Following are terms that may be encountered in practice:

- American Standards Institute (ANSI): The standard-setting body that approves the character sets and processing protocols used in computing.
- American Standard Code for Information Interchange (ASCII): The code set that is the basic foundation of technology.
- Cookie: A packet of data passed from one computer application to another and stored to be retrieved later.
- Electronic health record (EHR): A longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting.
- Electronic medical record (EMR): The legal record created in hospitals and ambulatory environments that is the source of data for the EHR.
- Relational database management system (RDBMS): This is a database management system in which data are stored in the form of tables and the relationship among the data is also stored in the form of tables.
- File transfer protocol (FTP): This is the simplest and most secure way to exchange files over the Internet. When *downloading* a file from the Internet you're actually *transferring* the file to your computer

from another computer over the Internet, representing the "T" (transfer) in FTP.

- Hypertext markup language (HTML): The language recognized for Web page development.
- Extensible markup language (XML): The language currently in the forefront of Web development.
- Health level seven (HL7): Used to define messages for laboratory and other clinical results and an ANSI-approved clinical message standard used in the United States and internationally.
- Logical Observations Identifiers Names and Codes (LOINC): A standard that identifies clinical questions, variables, and reports.
- Systematized Nomenclature of Medicine (SNOMED): Identifies procedures and possible answers to questions regarding test results.
- Wireless fidelity (WiFi): A radiofrequency standard used to connect devices, such as computers, using a wireless connection, replacing cables in the connection process.

IPs collect and manage large amounts of data. Effective use of the data is the fundamental element of a successful program. Information technology is used extensively in the day-to-day activities of the IP as the demand for more data continues to increase. Information technology comes in many forms; therefore, it is helpful for the IP to be familiar with some of the basic terms and concepts. These include the following:

- Hardware: The differences among a mainframe computer, network computer, personal computer, laptop, and handheld device primarily relate to their storage capacity, speed, cost, connectivity, typical users, and typical uses. Most computers include a central processing unit (CPU), memory (random-access memory [RAM], and read-only memory [ROM]), hard drive, one or more removable storage device (i.e., disk, CD or DVD drive, memory card, flash or jump drive), and networking or communications devices (network card, modem, etc.). Newer devices can operate using flash memory and contain very little internal memory capability. Most laptops use built-in wireless functions, thereby eliminating the need for external wireless cards. The typical computer also includes such input devices as a mouse, keyboard, scanner, touchpad, or stylus, and such output devices as a visual display unit, monitor, audio speakers, and printer.
- Interface: Communication with two independent systems requires an interface. An interface can be hardware, software, or user interfaces.
- Software: Software typically includes the operating system, networking software, and application software such as word processors, spreadsheets, databases, presentation tools, email processors, Web browsers, desktop publishing programs, and multimedia applications.
- Networking: Local area networks (LANs) connect computers within a single site, and wide area networks (WANs) link computers in multiple sites. Intranets are contained as internal networks for storing and sharing data. Many intranets use structured query language (SQL) platforms. Networking is also fostered by integrated service digital network (ISDN) connections, satellite communications, public switched data network (PDSN) systems, modems, digital connections, and wireless devices.
- The Internet: The World Wide Web, email, and search engines facilitate the transfer of data among computers and users.
- Security, privacy, and copyright: Rapid advances in our ability to share data continue to test data security measures. Securing individual and corporate data stored on personal and network computers challenges current infrastructures and requires continuous monitoring. The ability to readily retrieve information from the Internet also raises concern over copyright infringement and potential manipulation of a software product for personal use. Most healthcare facilities employ a security officer in their information technology department whose primary focus is data security.

## INFORMATION TECHNOLOGY

### *How Computers Work*

#### *Hardware*

Hardware in computer terms refers to a mainframe or central computer that acts as the primary device for management of multiple individual users. A server is a computer or device specifically designed for a certain task.<sup>29</sup> An example of a server is a file server dedicated to the storage of files. This type of server can be accessed by individuals wanting to store information in a secure place, typically on a LAN. Servers are designed to perform only certain tasks; however, their capabilities are expanded when used in a multioperating system. Multioperating systems are capable of supporting hundreds of users, and the mainframe or server may support a range of devices, including personal computers, laptops, workstations, wireless and handheld devices, and telecommunications and telephony systems.

Regardless of size or speed, all computers rely on a central processing unit (CPU) to control all functions, basic and advanced. The CPU is the "brain" of the computer and is responsible for managing the transfer of data from one part of the computer to another and performs multiple functions, such as process control, arithmetic and logic, memory access, decoding, buffering, and storage. CPUs are known more commonly as processors or microprocessors and are the most important component of a computer.

The computer relies on two types of internal memory. ROM is built-in memory that contains data and programming that are required to make the computer operate ("booted" on startup or refreshed on login). ROM can be read but not written by the computer. RAM is available to the computer for various processing and storage functions. Memory is measured by the amount of data processed in a given time period in bits, bytes, kilobytes (KB), megabytes (MB), gigabytes (GB), terabytes (TB), and more.

The CPU speed, amount of RAM, and processing (hard drive) speed and capacity affect the computer's overall performance.

#### *Software*

Software is a computer program that provides the instructions that enable the hardware to work. Operating software or system software is the platform or framework that drives the computer. The operating system (OS) controls the underlying function of a computer, including the interplay of the various hardware and software components. A common operating system for personal computers and business networks is Windows, developed by Microsoft. Computers and other devices made by Apple Computer rely on the Mac OS. Certain handheld devices utilize the Palm OS or Windows Mobile. Newer generations of consumer electronics and appliances are also incorporating one or more operating systems to make them compatible with other networked devices.

Some operating systems include basic applications such as text writing and editing, installation of hardware and peripherals, networking, a calculator, and basic audio and video functions. Most users, however, rely on other software applications such as word processors, spreadsheets, databases, presentation tools, email processors, Internet browsers, and multimedia programs.

#### *Data Collection, Management, and Reporting*

Infection prevention relies on data to drive improvement efforts. Data are elements of a total entity, and each piece of data can affect an outcome on a variety of levels. For example, collection of raw data

such as a line listing of patients with multidrug-resistant organisms can provide essential information for investigation of a suspected outbreak. From the line listing, more detailed analysis can then be performed such as calculation of monthly incidence (e.g., frequency per 1,000 patient days) of select microorganisms of epidemiological importance in the facility sorted by patient unit.

Once collected, data must be put in an accessible and stable database to be useful. An IP typically uses the same data for multiple reports and purposes, such as surveillance, managing infections, patient safety, and sentinel event reporting. A well-organized database is tremendously powerful and can provide the information needed to monitor and perhaps curtail the spread of infection.

### *Data Collection*

Daily surveillance requires the collection, review, analysis, and storage of data. Any data collection form should be standardized to eliminate duplicate efforts and prevent misinterpretation by the data collector(s). Formatting for ease of use facilitates correct data collection and eliminates missing data.

Scanned forms are fairly easy to develop using specialized software programs, but they may be difficult to use and to modify, and only provide users with a static copy of the information. Printed laboratory reports are of limited use because the data must be extracted and stored elsewhere. Retrieval of data can now occur with the use of the EHR. Healthcare facilities are moving away from the paper patient medical record and more toward the electronic record. The medical informatics professionals realized the need for interoperability of EHRs and created standards for data coding and communication.<sup>30</sup> The

Office of the National Coordinator for Health IT (ONC) authorized certification bodies that provide a certification process for EHRs so that interoperability is improved and allow decision-makers the ability to adopt EHRs more easily. Information regarding these certification processes can be found at the Certification Commission for Healthcare Information Technology website.<sup>31</sup> Potential utilization of the EHR for surveillance of HAIs has recently been reviewed.<sup>25</sup>

The optimal collection method would be seamless and transparent to the user—one that enables the laboratory systems to "talk" or interface with other computer systems—but such systems are impractical for most IPs because of the need for advanced computer skills, the high costs of programming, and the amount of equipment required. The need to retrieve and access large amounts of data specific to a particular patient population has prompted organizational leaders to review surveillance systems. The IP is poised to take the lead on reviewing the proposed systems and offering recommendations to the capital committees and executives. The IP should be familiar with the terms necessary to converse with the IT department and serve as the liaison between them and the vendor offering the system. Infection preventionists should be part of the implementation team to ensure the needs of the department are met during the system initialization. Changes made after implementation are more difficult, and organizations can incur additional expenses.

For institutions that are not ready or unable to purchase a system, there are relatively inexpensive and easy-to-use data collection and management tools available. The CDC offers data storage, retrieval, and analysis through NHSN. NHSN replaced the National Nosocomial Infection Surveillance System (NNIS) and offers Web-based interoperability. NHSN, as a reporting tool, also provides a means by which the IP can use datasets of entered data and customize data analysis and reports. The options in NHSN include line listings, control charts with aggregated data averages, and optional in-depth analysis using embedded SAS analytics. The capabilities of NHSN are increasing as more states and CMS legislative mandates are requiring public reporting using NHSN. Growing from an initial base of 300 hospitals in 2005 to over 2,000 by November 2008, there were 4,444 enrolled healthcare facilities reporting at least



1 month of denominator data into NHSN in 2012.<sup>32</sup> Some of this is attributable to legislative mandates for public reporting of HAI data; however, a substantial portion is unrelated to these requirements. This growth in NHSN enrollees also is occurring in smaller hospitals, resulting in a more diverse and accurate picture of the epidemiology of HAIs in all acute care settings.

### *Data Management*

Most database management systems allow users to enter, edit, view, and print data from one or more tables. This may make the database appear similar to a spreadsheet application, but there are three distinct differences between a relational database management system (RDBMS) and a spreadsheet application. First, a relational database is designed to handle large amounts of data efficiently. Second, in a relational database, two or more tables can be easily linked and can be viewed as one, as illustrated in Figure 6-1. Finally, a relational database repeats only data that link other components, thereby minimizing the duplication of information.

When developing a database, clinical and information systems personnel must consider the following elements:

- Selection of a primary key or identifier (e.g., patient medical record or billing number): The unique identifier enables records to be sorted and linked. Many database applications automatically assign a unique number to each record as it is created.
- Categorization of the information: Label data appropriately to foster rapid searching.
- Providing ready access to the data, but protecting its security: If a number of individuals need access to the database, its location becomes a strategic decision. For example, a database that must be shared by multiple users may be stored on a network server rather than on a local hard drive. However, it may be necessary or prudent to limit access to the database by using passwords in order to control and preserve the integrity of the data.
- Retrieval of the data: Create filters to isolate records that match a defined set of criteria, and use sorting to organize the records in a specific order based on the contents of one or more fields. Sorting can be done alphabetically, numerically, or by specified characteristics (i.e., male or female). It is advantageous to use these simple functions whenever possible to provide a standardized format for viewing. Sorting and filtering can be used to provide a standard format for viewing the data. Most database applications include these functions on the toolbar.
- Queries to link data elements: Create several tables related to the original records to enable more efficient and productive use of the data for case investigation and epidemiological research. Tables may be based on a "one-to-one" or a "one-to-many" relationship. One-to-many relationships are inherently more powerful. For instance, there may be a link between a line listing of patients with multidrug-resistant organisms and a table with reportable disease findings or bloodstream infections.
- Back up of data: The database should be regularly copied or backed up. Frontend storage refers to the process of backing up the data locally, for example, using a hard drive, CD, or a DVD or external backup device. Backend storage refers to larger systems used to back up data from multiple computers or entire networks. Backing up data is crucial and should be the first consideration when developing a database. Lost data are difficult and expensive to retrieve if that option is even available.
- Export and import of data as appropriate: Data may need to be shared internally and externally in a format that can be used by other software applications. Most often, this requires converting the data from a database format into another format such as a text file, spreadsheet, or table.

- Analysis of the data
- Reporting of the data
- Integration of a macro-enabled system for checking errors: Macros are used to define a sequence of actions that automate repetitive database functions, including opening, printing, and closing certain reports each time a command is executed. Most database applications include some reporting macros. Others can be written or purchased.

### *Data Analysis*

Analyzing data can be cumbersome, labor intensive, and sometimes frustrating. Most analysis is conducted using queries, which are questions asked of the data. There are several types of queries, as follows:

- "Select" queries extract data from one or more tables and display them in a tabular form.
- "Crosstab" queries summarize data from one or more tables in the form of a spreadsheet.
- "Action" queries create new tables from query tables or make major changes to already-defined tables.
- "Parameter" queries use a single query over and over and only make simple changes to the original table.

It is extremely important that any analysis be validated to ensure the integrity and quality of the data. Using the right software also maximizes the usefulness of the data. Infection prevention departments should focus on moving from a data-rich, information-poor (DRIP) environment to a recognized resource for accurate and timely data. This includes choosing software that matches the needs and comfort level with technology of the end users. The following are three of the most widely used statistical analysis software applications:

- S-Plus: A software package designed for exploratory data analysis and statistical mining; a flexible program capable of high-powered data analysis.
- SAS: A suite of software for information delivery that is built around four common tasks (data access, management, analysis, and presentation); additional components can be added later.
- SPSS: Software designed for data access, data preparation, analytical reporting, statistics, and predictive modeling.

Although these programs are used for data analysis, they may require more specialized training; therefore, the IP should use software that is familiar yet powerful, such as spreadsheet or relational database software.

### *Data Reporting*

Reporting is usually the final step in most database applications. How data are reported can affect their impact. Good reports make key information and conclusions readily identifiable to the intended audience. A data report typically contains (1) the topic (what the report is about); (2) a one-sentence summary of the data; (3) the date of the report, to coincide with the date the final data were gathered; (4) the report period (start date to end date); (5) titles of rows or categories (types of data and relation to other data); and (6) page numbers and other reference points.

Graphs can provide a sequential method for displaying data and can facilitate the tracking of trends. There are several types of graphs and charts, including line charts, pie charts, bar graphs, control

charts, line graphs, run charts, stacked area charts, stacked column charts, and histograms.

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# Guide to Infection Prevention in Emergency Medical Services



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APIC's mission is to create a safer world through prevention of infection. The association's more than 14,000 members direct infection prevention programs that save lives and improve the bottom line for hospitals and other healthcare facilities. APIC advances its mission through patient safety, implementation science, competencies and certification, advocacy, and data standardization.



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APIC Implementation Guides help infection preventionists apply current scientific knowledge and best practices to achieve targeted outcomes and enhance patient safety. This series reflects APIC's commitment to implementation science and focus on the utilization of infection prevention research. Topic-specific information is presented in an easy-to-understand-and-use format that includes numerous examples and tools.

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# Table of Contents

Acknowledgments . . . . .	4
Declarations of Conflicts of Interest and Disclaimer. . . . .	6
Introduction. . . . .	8
Section 1: Guide Overview. . . . .	9
Section 2: Epidemiology and Pathogenesis: Infectious Diseases in EMS . . . . .	12
Section 3: Risk Factors/Risk Assessment in EMS . . . . .	23
Section 4: Surveillance . . . . .	28
Section 5: Engineering and Work Practice Controls and Personal Protective Equipment . . . . .	32
Section 6: Occupational Exposure Health Issues. . . . .	43
Section 7: Bioterrorism and Infectious Disease Emergency Preparedness . . . . .	65
Section 8: Education, Training, Compliance Monitoring, and Summary . . . . .	71
Appendix A: Sample Ambulance Cleaning Procedures . . . . .	78
Appendix B: Sample Exposure Control Plan . . . . .	80
Appendix C: Definition of Terms . . . . .	83
Appendix D: Acronyms and Abbreviations. . . . .	86

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Katherine H. West, BSN, MEd, CIC, has nothing to declare.

## Disclaimer

The *Guide to Infection Prevention in Emergency Medical Services* is advisory and informational and is intended to assist and guide EMS agencies, including Public Safety and Fire, in providing a safe workplace through effective Infection Prevention programs adapted to the needs of EMS system responders. Although many regulations are introduced in this guide, each EMS agency should be familiar with, implement, and comply with state and federal regulatory requirements.

It is the intent of APIC to enhance access of infection prevention information through the content, references, and resources contained within this guide. Resources are continuously being updated, and APIC has made every effort to present the most current information, including information maintained by other public and private organizations. This information is useful; however, APIC cannot guarantee the accuracy, relevance, timeliness, or completeness of information developed from outside sources.



# Introduction

Emergency Medical Services (EMS) system responders deliver medical care in many unique and oftentimes dangerous environments. They render care to increasingly mobile populations who potentially have a higher likelihood of having an infectious or emerging disease. In addition to treating accident victims of every nature (vehicular, falls, cuts, burns, and more), they treat the homeless, nursing home patients, trauma victims, and the critically ill with multiple diseases and infections. They have unique concerns such as suspect searches, communal living arrangements, and the need to clean and disinfect their work equipment. Like many other healthcare professionals, they face ever-increasing exposures to infectious diseases.

Many of the agencies that employ EMS system responders are not hospital-based and therefore may not have the same knowledge of the importance of infection prevention as healthcare facilities. Many EMS agencies lack funding and have limited staffing. Infection prevention resources exist, but they are not easy to find. Resources for EMS system responders, such as the *United States Fire Administration Guide to Managing an Emergency Service Infection Control Program* (2002) and *Infectious Diseases and the*

*Fire and Emergency Services* (2001), are out of date and many changes have taken place since they were published. APIC saw a need to develop this Infection Prevention Guide because EMS agencies, including public safety and fire, needed a comprehensive, easy-to-use guide to serve as a resource to develop or enhance their current knowledge of infection prevention strategies. The information contained in this guide is intended as a roadmap to develop a comprehensive infection prevention program.

For the purpose of this guide, all EMS personnel will be referred to as EMS system responders. This group encompasses all paid and volunteer paramedics and emergency medical technicians (EMTs) on ambulances, first responders, fire paramedics and firefighter EMTs, police, and public safety officers. Although most EMS issues are similar, there are some differences among EMS system responders. Every effort has been made to address those differences.

This *Guide to Infection Prevention in EMS* is intended to assist in keeping EMS system responders and the patients they care for safe and healthy while reducing their exposure risks.

# Section 1: Guide Overview

## Purpose and scope

The purpose of this guide is to provide Emergency Medical Services (EMS) system responders and their organizations with a practical resource to infection recognition and prevention in the EMS environment. This guide contains current information, recommendations, regulations, resources, program examples, and forms to utilize in the EMS system responder setting.

## Key concepts

- Infection preventionists (IPs) are healthcare professionals who have special training in infection prevention and monitoring.
- Many of the principles and practices that hospital IPs employ for infection prevention can and should be used in EMS settings, whether it be a fire department, police agency, or public or private ambulance company.
- EMS system responders are exposed to all manners of infectious diseases and must be trained to recognize them and prevent their spread.
- Designated Infection Control Officers (DICOs) are healthcare professionals who work for EMS agencies, have special training, and serve as their agencies' IP. Federal law requires agencies have a designated DICO.
- The DICO must be up to the challenging tasks of keeping current on infection prevention topics, conducting ongoing research, and updating procedures and policies as necessary.

- Although compliance with infection prevention standards may seem complex, this guide will attempt to simplify the process and explain why utilizing the guide is the key to a safe workplace.
- EMS leadership must support infection prevention staff and the development of infection prevention programs in compliance with laws and regulations. Leadership support is critical to successful implementation of basic infection prevention strategies.

## Infection prevention

Created in hospitals and clinics, infection prevention training has by necessity expanded to include EMS system responders and out-of-hospital emergency medical care agencies. Infection prevention programs are designed to prevent the transmission of infectious disease agents and to provide a safe work environment for healthcare personnel and their patients.

Infection prevention programs both inside and outside the hospital setting should contain six major components:

- Administrative controls
- Engineering controls
- Work practice controls
- Education
- Medical management
- Vaccine/immunization program

These components will be discussed later in the guide.

Although there are articles, references, and guides available on infection prevention in EMS, infection prevention is limited because the expertise and resources are not present in many agencies. EMS agencies have known about bloodborne pathogens for years. However, it has only been in the last 5 to 6 years that articles describing methicillin-resistant *Staphylococcus aureus* (MRSA) in ambulances and fire stations have appeared in fire and EMS literature along with ways to prevent exposures. Two studies found in the *American Journal of Infection Control* address the transmission and carriage of MRSA within the fire department and ambulance environments. The University of Washington Department of Environmental and Occupational Health Services stated that fire and ambulance personnel have the unique opportunity to acquire and transfer infections from both hospital and community sources.<sup>1</sup> James V. Rago, PhD, and his team from Lewis University and Orland Fire Protection District, found that 70 percent of ambulances in the Chicago metropolitan area contained at least one strain of *S. aureus* bacteria.<sup>2</sup>

Infection prevention in the public safety sector is challenging. Because the scope of public safety members' duties has expanded, there is an increased need to develop awareness and education.

In most states, police agencies fall under the Occupational Safety & Health Administration (OSHA), Ryan White Notification Law, and infection prevention umbrella like other EMS system responders. However, they often have less training and minimal or no personal protective equipment (PPE) when they respond to a medical emergency or when they encounter a person with open wounds, blood, or infectious diseases.

The National Institute for Occupational Safety and Health (NIOSH) completed national surveys that reveal a high incidence of exposures to bloodborne pathogens for paramedics.<sup>3</sup> Recent articles discuss the underreporting of exposures, the lack of safety equipment, the lack of PPE, and the lack of training in the use of PPE.<sup>3</sup>

This guide contains standards and regulatory information along with easy-to-follow templates and forms that can be used to develop an Exposure Control Plan and conduct infectious disease surveillance, risk assessments, and postexposure management, as well as monitor compliance.

The treatment of exposures and injuries for EMS system responders has expanded significantly with the institution of occupational doctors, health nurses, safety chiefs, and other DICOs to oversee personnel health services. These groups have developed alliances with local hospitals and county health departments to ensure appropriate postexposure follow-up. They ensure exposures are handled within accepted treatment guidelines.

Unfortunately, many departments, counties, and states do not have the funding needed for education and training in infection prevention. Some municipal hospitals provide this service and training free to EMS, police, and fire agencies. This guide has included some resources and websites that provide courses, online training, sample programs, and other information regarding infection prevention.

EMS system responders are prepared for disasters and bioterrorism to varying degrees, but are largely dependent on the available resources and expertise within their EMS agencies. Larger municipal, metropolitan, and regional systems are often perceived as more prepared to deal with disaster and bioterrorism situations. Although there is increased awareness of bioterrorism incidents throughout the United States since September 11, 2001, no one can be truly prepared for all the hazards they could encounter during a bioterrorism event. This guide provides an overall view of the types of major biological weapons that might be encountered, types of PPE, and ways to protect one's self and others.

Although EMS system responders acknowledge the importance of protocols for cleaning and disinfecting equipment, several articles in EMS trade journals cite contamination of fire

stations, ambulances, and equipment, such as with MRSA.<sup>4, 5</sup> OSHA compliance monitoring requirements are presented later in the guide.

The major goal of this guide is to increase awareness, educate, and provide guidance to EMS system responders who are at risk for occupational exposure to blood, other potentially infectious materials, infectious diseases, and bioterrorism. Standard EMS training curriculum contains information on infection prevention. However, EMS needs more integration with other community IPs and more efficient communication networks for information sharing. It is our sincere hope that this guide helps ensure a safer environment for both EMS system responders and the patients they care for in the community.

2 Rago RV, Buhs K, Makarovaite V, Patel E, Pomeroy M, Yasmine C. Detection and analysis of *Staphylococcus aureus* isolates found in ambulances in the Chicago metropolitan area. *Am J Infect Control* 2012 Apr;40(3):201-205.

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4 Merlin AM, Wong ML, Pryor PW, Ryan K, Marques-Baptista A, Perritt R, et al. Presence of methicillin-resistant *Staphylococcus aureus* on the stethoscopes of EMS providers. *Prehosp Emerg Care* 2009 Jan-Mar;13(1):71-74.

5 Roline CE, Rumpecker C, Dunn TM. Can methicillin resistant *Staphylococcus aureus* be found in an ambulance fleet? *Prehosp Emerg Care* 2007 Apr-June;11(2):241-243.

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## Section 2: Epidemiology and Pathogenesis: Infectious Diseases in EMS

### Key concepts

- Effective efforts to eliminate or reduce bloodborne and infectious disease exposures and transmission are guided by the epidemiology (causes and distribution) of those diseases.
- Communicable diseases can be passed from one person to another. Infectious disease can cause illness in a person but is not necessarily communicable.
- The current infectious disease burden for the agency and setting is found by conducting an environmental risk assessment.
- EMS agencies must ensure all EMS system responders report to work healthy. They must have a written plan in place outlining work restriction guidelines when EMS system responders contract and/or are exposed to an infectious disease.
- EMS agencies must ensure all EMS system responders have the necessary immunizations or written proof of immunity to protect them against infectious diseases.

### Background

Epidemiology is defined as the study of the distribution and determinants of health-related states in specified populations, and the application of this study to control health problems.<sup>1</sup> Epidemiology includes outbreak investigation, disease surveillance, and

screening and comparison of treatment effects. Pathogenesis of a disease is the mechanism by which the disease is caused.

The Centers for Disease Control and Prevention (CDC), through the Ryan White Act, is charged with keeping a list of potentially life-threatening diseases that must be reported by medical facilities to EMS agencies when one of those diseases is found in a patient transported to their facility. This list reflects diseases that have been around for many years and diseases that have recently re-emerged (see Table 2.1). EMS agencies should also be aware of nonreportable diseases that threaten their workforce.

In the Guideline for Infection Control in Health Care Personnel 1998, the CDC recognized EMS system responders as being at risk for acquiring infections from or transmitting infections to patients, other personnel, household members, or other community contacts.<sup>2</sup> The DICO or personnel health services should arrange for the prompt diagnosis of job-related illnesses and postexposure prophylaxis after job-related exposures. Decisions on work restrictions are based on mode of transmission and epidemiology of the disease (Table 2.2). Exclusion policies should contain a statement of authority defining who can exclude personnel and should be designed to encourage personnel to report their illnesses or exposures without penalizing them with loss of wages, benefits, or job status.

**Table 2.1.** List of potentially life-threatening infectious diseases to which emergency response employees may be exposed

Diseases routinely transmitted by contact or body fluid exposures	Diseases routinely transmitted through aerosolized airborne means	Diseases routinely transmitted through aerosolized droplet means	Diseases caused by agents potentially used for bioterrorism or biological warfare
Anthrax, cutaneous ( <i>Bacillus anthracis</i> )	Measles (Rubeola virus)	Diphtheria ( <i>Corynebacterium diphtheriae</i> )	These diseases include those caused by any transmissible agent included in the HHS Select Agents List
Hepatitis B (HBV)	Tuberculosis ( <i>Mycobacterium tuberculosis</i> )—infectious pulmonary or laryngeal disease; or extrapulmonary (draining lesion)	Novel influenza A viruses as defined by the Council of State and Territorial Epidemiologists (CSTE)	
Hepatitis C (HCV)	Varicella disease ( <i>Varicella zoster</i> virus)—chickenpox, disseminated zoster	Meningococcal disease ( <i>Neisseria meningitidis</i> )	
Human immunodeficiency virus (HIV)		Mumps (Mumps virus)	
Rabies (Rabies virus)		Pertussis ( <i>Bordetella pertussis</i> )	
Vaccinia (Vaccinia virus)		Plague, pneumonic ( <i>Yersinia pestis</i> )	
Viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, and other viruses yet to be identified)		Rubella (German measles; Rubella virus)	
		SARS-CoV	

Adapted from National Institute for Occupational Safety and Health. List of potential life-threatening diseases.<sup>3</sup>

**Table 2.2.** Summary of suggested work restrictions for healthcare personnel exposed to or infected with infectious diseases of importance in healthcare settings, in the absence of state and local regulations

Disease/problem	Work restriction	Duration	Category
<b>Conjunctivitis</b>	Restrict from patient contact and contact with the patient's environment	Until discharge ceases	II
<b>Cytomegalovirus infections</b>	No restriction		I
<b>Diarrheal diseases</b> Acute stage (diarrhea with other symptoms)	Restrict from patient contact, contact with the patient's environment, or food handling	Until symptoms resolve	I IB

(continued)



**Table 2.2.** Summary of suggested work restrictions for healthcare personnel exposed to or infected with infectious diseases of importance in healthcare settings, in the absence of state and local regulations, continued

Disease/problem	Work restriction	Duration	Category
Convalescent stage, <i>Salmonella</i> spp.	Restrict from care of high-risk patients	Until symptoms resolve; consult with local and state health authorities regarding need for negative stool cultures	IB
<b>Diphtheria</b>	Exclude from duty	Until antimicrobial therapy completed and 2 cultures obtained 24 hours apart are negative	IB
<b>Enteroviral infections</b>	Restrict from care of infants, neonates, and immunocompromised patients and their environments	Until symptoms resolve	II
<b>Hepatitis A</b>	Restrict from patient contact, contact with patient's environment, and food handling	Until 7 days after onset of jaundice	IB
<b>Hepatitis B</b> Personnel with acute or chronic hepatitis B surface antigenemia who do not perform exposure-prone procedures  Personnel with acute or chronic hepatitis B e antigenemia who perform exposure-prone procedures	No restriction; refer to state regulations; Standard Precautions should always be observed  Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of worker; refer to state regulations	Until hepatitis B e antigen is negative	II
<b>Hepatitis C</b>	Restrict only from Class III procedures		II
<b>Herpes simplex</b> Genital Hands (herpetic whitlow)  Orofacial	No restriction Restrict from patient contact and contact with the patient's environment  Evaluate for need to restrict from care of high-risk patients	Until lesions heal	II IA
<b>Human immunodeficiency virus</b>	Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of the worker; standard precautions should always be observed; refer to state regulations		

(continued)

**Table 2.2.** Summary of suggested work restrictions for healthcare personnel exposed to or infected with infectious diseases of importance in healthcare settings, in the absence of state and local regulations, continued

Disease/problem	Work restriction	Duration	Category
<b>Measles</b>			
Active	Exclude from duty	Until 7 days after the rash appears	IA
Postexposure (susceptible personnel)	Exclude from duty	From 5th day after 1st exposure through 21st day after last exposure and/or 4 days after rash appears	IB
<b>Meningococcal infections</b>	Exclude from duty	Until 24 hours after start of effective therapy	IA
<b>Mumps</b>			
Active	Exclude from duty	Until 9 days after onset of parotitis	IB
Postexposure (susceptible personnel)	Exclude from duty	From 12th day after 1st exposure through 26th day after last exposure or until 9 days after onset of parotitis	II
<b>Pertussis</b>			
Active	Exclude from duty	From beginning of catarrhal stage through 3rd wk after onset paroxysms or until 5 days after start of effective antimicrobial therapy	IB
Postexposure (asymptomatic personnel)	No restriction; prophylaxis recommended		I
Postexposure (symptomatic personnel)	Exclude from duty	Until 5 days after start of effective antimicrobial therapy	IB
<b>Rubella</b>			
Active	Exclude from duty	Until 5 days after rash appears	IA
Postexposure (susceptible personnel)	Exclude from duty	From 7th day after 1st exposure through 21st day after last exposure	IB
<b>Scabies</b>	Restrict from patient contact	Until cleared by medical evaluation	IB
<b><i>Staphylococcus aureus</i> Infection</b>			
Active, draining skin lesions	Restrict from contact with patients and patient's environment or food handling	Until lesions have resolved	IB
Carrier state	No restriction, unless personnel are epidemiologically linked to transmission of the organism		IB

(continued)

**Table 2.2.** Summary of suggested work restrictions for healthcare personnel exposed to or infected with infectious diseases of importance in healthcare settings, in the absence of state and local regulations, continued

Disease/problem	Work restriction	Duration	Category
<b>Streptococcal infection, group A</b>	Restrict from patient care, contact with patient's environment, or food handling	Until 24 hours after adequate treatment started	IB
<b>Tuberculosis</b> Active disease PPD converter	Exclude from duty No restriction	Until proved noninfectious	IA IA
<b>Varicella</b> Active	Exclude from duty	Until all lesions dry and crust	IA
Postexposure (susceptible Personnel)	Exclude from duty	From 10th day after 1st exposure through 21st day (28th day if VZIG given) after last exposure	IA
<b>Zoster</b> Localized, in healthy person	Cover lesions; restrict from care of high-risk patients†	Until all lesions dry and crust	II
Generalized or localized in immunosuppressed person	Restrict from patient contact	Until all lesions dry and crust	IB
Postexposure (susceptible personnel)	Restrict from patient contact	From 10th day after 1st exposure through 21st day (28th day if VZIG given) after last day exposure or, if Varicella occurs, until all lesions dry and crust	IA
<b>Viral respiratory infections, acute febrile</b>	Consider excluding from the care of high-risk patients‡ or contact with their environment during community outbreak of RSV and influenza	Until acute symptoms resolve	IB

\*Unless epidemiologically linked to transmission of infection

†Those susceptible to varicella and who are at increased risk of complications of varicella, such as neonates and immunocompromised persons of any age.

‡High-risk patients as defined by the ACIP for complications of influenza.

As in previous CDC guidelines, each recommendation is categorized on the basis of existing scientific data, theoretic rationale, applicability, and potential economic impact. The system for categorizing recommendations is as follows:

Category IA - Strongly recommended for all hospitals and strongly supported by well-designed experimental or epidemiologic studies.

Category IB - Strongly recommended for all hospitals and reviewed as effective by experts in the field and a consensus of Hospital Infection Control Practices Advisory Committee members on the basis of strong rationale and suggestive evidence, even though definitive scientific studies have not been done.

Category II - Suggested for implementation in many hospitals. Recommendations may be supported by suggestive clinical or epidemiologic studies, a strong theoretic rationale, or definitive studies applicable to some but not all hospitals.

No recommendation; unresolved issue - Practices for which insufficient evidence or consensus regarding efficacy exists.

Source: Bolyard EA, Tablan OC, Williams WW, Pearson ML, Shapiro CN, Deitchman SD, et al. Guideline for infection control in healthcare personnel, 1998. Centers for Disease Control and Prevention. Available at: [www.cdc.gov/hicpac/pdf/InfectControl98.pdf](http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf)

## Immunization programs

Ensuring that personnel are immunized against vaccine-preventable diseases is an essential part of successful personnel health programs, and OSHA is enforcing the CDC immunization guidelines (Table 2.3). Immunization can prevent transmission of vaccine-preventable diseases and eliminate unnecessary work restriction. Prevention of illness through comprehensive personnel immunization programs is far more cost-effective than case management, outbreak control, sick leave, and replacement costs.

Decisions about vaccines to include in immunization programs have been made by considering the following:

- (a) The likelihood of personnel exposure to vaccine-preventable diseases and the potential consequences of not vaccinating personnel
- (b) The nature of employment (type of contact with patients and their environment)
- (c) The characteristics of the patient population within the healthcare organization
- (d) Nationally accepted standards such as NFPA 1581 (NFPA 1581, Standard on Fire Department Infection Control Program) and 1582 (Standard on Comprehensive Occupational Medical Program for Fire Departments).

## Example of epidemiology, pathogenesis, and transmission

*Staphylococcus aureus* is found on the skin of humans as part of our normal body flora. It is estimated that nasal colonization in the general U.S. adult population is 25 to 30 percent.<sup>4</sup> *S. aureus* from nasal colonization can be transferred to skin and other body areas. An infection occurs when a breach in the skin allows staph bacteria to enter. Methicillin-

resistant *S. aureus* (MRSA) is a strain of staph bacteria that is resistant to  $\beta$ -lactam antibiotics.

Until the late 1990s MRSA was predominately found in hospitals. However, starting in the late 1990s, MRSA infections were increasingly found in populations with no known healthcare-associated risks for acquisition.<sup>5</sup> These cases were labeled community-acquired MRSA (CA-MRSA). According to the International Association of Fire Fighters, MRSA is considered a serious threat to EMS system responders.<sup>6</sup> Because EMS system responders bridge the community and healthcare settings, they are at high risk for contracting and transmitting MRSA.

Although hospital-associated MRSA infections are tracked, most EMS agencies do not have the processes in place to track cases of CA-MRSA. In order to implement interventions to reduce or eliminate MRSA, total number of cases each year should be tracked along with all associated medical costs.

## Strategies to prevent transmission of MRSA and other infectious diseases

Documentation shows MRSA transmission both directly from infected and colonized patients and indirectly via contaminated equipment, supplies, and environmental surfaces. Standard Precautions is the first step in prevention, as is identification of common transmission routes. When the sources of transmission are identified, infection prevention staff or the DICO should implement a series of focused interventions including the following:

- Education in infection prevention
- Proper and frequent use of disinfectants
- Hand hygiene and the appropriate use of gloves
- Replacement of cloth surfaces with hard surfaces

**Table 2.3.** Immunobiologics and schedules and immunizing agents strongly recommended for healthcare personnel

Generic name	Primary booster dose schedule	Indications	Major precautions and contraindications	Special considerations
Hepatitis B recombinant vaccine	Two doses IM in the deltoid muscle 4 weeks apart; third dose 5 months after second; booster doses not necessary	Healthcare personnel at risk of exposure to blood and body fluids	No apparent adverse effects to developing fetuses, not contraindicated in pregnancy; history of anaphylactic reaction to common baker's yeast	No therapeutic or adverse effects on HBV-infected persons; cost-effectiveness of prevaccination screening for susceptibility to HBV depends on costs of vaccination and antibody testing and prevalence of immunity in the group of potential vaccines; healthcare personnel who have ongoing contact with patients or blood should be tested 1–2 months after completing the vaccinations series to determine serologic response
Influenza vaccine (inactivated whole or split virus)	Annual single-dose vaccination IM with current (either whole or split-virus) vaccine	Healthcare personnel with contact with high-risk patients or working in chronic care facilities; personnel with high-risk medical conditions and/or $\geq 65$ years	History of anaphylactic hypersensitivity after egg ingestion	No evidence of maternal or fetal risk when vaccine was given to pregnant women with underlying conditions that render them at high risk for serious influenza complications
Measles live-virus vaccine	One dose SC; second dose at least 1 month later	Healthcare personnel born in or after 1957 without documentation of (a) receipt of two doses of live vaccine on or after their first birthday, (b) physician-diagnosed measles, or (c) laboratory evidence of immunity; vaccine should be considered for all personnel, including those born before 1957, who have no proof of immunity	Pregnancy; immunocompromised* state; (including HIV-infected) persons with severe immunosuppression) history of anaphylactic reactions after gelatin ingestions or receipt of neomycin; or recent receipt of immune globulin	MMR is the vaccine of choice if recipients are also likely to be susceptible to rubella and/or mumps; persons vaccinated between 1963 and 1967 with (a) a killed measles vaccine alone, (b) killed vaccine followed by live vaccine, or (c) a vaccine of unknown type should be revaccinated with two doses of live measles vaccine

**Table 2.3.** Immunobiologics and schedules and immunizing agents strongly recommended for healthcare personnel, continued

Generic name	Primary booster dose schedule	Indications	Major precautions and contraindications	Special considerations
Mumps live-virus vaccine	One dose SC; no booster	Healthcare personnel believed to be susceptible can be vaccinated; adults born before 1957 can be considered immune	Pregnancy; immunocompromised* state; history of anaphylactic reactions after gelatin ingestions or receipt of neomycin	Women pregnant when vaccinated or who become pregnant within 3 months of vaccination should be counseled on the theoretic risks to the fetus, the risk of rubella vaccine-associated malformations in these women is negligible; MMR is the vaccine of choice if recipients are also likely to be susceptible to measles or mumps
Rubella live-virus vaccine	One dose SC; no booster	Healthcare personnel, both male and female, who lack documentation of receipt of live vaccine on or after their first birthday, or of laboratory evidence of immunity; adults born before 1957 can be considered immune, except women of childbearing age	Pregnancy; immunocompromised* state; history of anaphylactic reaction after receipt of neomycin	Women pregnant when vaccinated or who become pregnant within 3 months of vaccination should be counseled on theoretic risks to the fetus, the risk of rubella vaccine-associated malformations in these women is negligible; MMR is the vaccine of choice if recipients are also likely to be susceptible to measles or mumps
Varicella zoster live-virus vaccine	Two 0.5 mL doses SC, 4–8 weeks apart if ≥13 years	Healthcare personnel without reliable history of varicella or laboratory evidence of varicella immunity	Pregnancy, immunocompromised* state, history of anaphylactic reaction after receipt of neomycin or gelatin; salicylate use should be avoided for 6 weeks after vaccination	Because 71%–93% of persons without a history of varicella are immune, serologic testing before vaccination may be cost-effective

IM, Intramuscular; SC, subcutaneously.

\*Persons immunocompromised because of immune deficiencies, HIV infection, leukemia, lymphoma, generalized malignancy, or immunosuppressive therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation.

Source: Bolyard EA, Tablan OC, Williams WW, Pearson ML, Shapiro CN, Deitchman SD, et al. Guideline for infection control in healthcare personnel, 1998. Centers for Disease Control and Prevention. Available at: [www.cdc.gov/hicpac/pdf/InfectControl98.pdf](http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf). Accessed January 24, 2013.



- Confinement of turnout gear to work areas
- Station wear kept at the station and laundered after use.

In addition, EMS system responders should use Standard Precautions as described below in Table 2.4 to prevent transmission of MRSA and other multidrug-resistant organisms.

## Contact Precautions for MRSA patients

In addition to Standard Precautions described, CDC recommends using Contact Precautions if a patient is known to be colonized with MRSA or has an active MRSA infection. In general, Contact Precautions will be applied once the patient is admitted to the hospital. However,

**Table 2.4.** Recommendations for application of standard precautions for the care of all patients in all healthcare settings<sup>7</sup>

Component	Recommendations
<b>Hand hygiene</b>	After touching blood, body fluids, secretions, excretions, contaminated items; immediately after removing gloves; between patient contacts
<b>Personal protective equipment (PPE)</b>	
<b>Gloves</b>	For touching blood, body fluids, secretions, excretions, contaminated items; for touching mucous membranes and nonintact skin
<b>Gown</b>	During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated
<b>Mask, eye protection (goggles), face shield*</b>	During procedures and patient-care activities likely to generate splashes or sprays of blood, body fluids, secretions, especially suctioning, endotracheal intubation
<b>Soiled patient-care equipment</b>	Handle in a manner that prevents transfer of microorganisms to others and to the environment; wear gloves if visibly contaminated; perform hand hygiene
<b>Environmental control</b>	Develop procedures for routine care, cleaning, and disinfection of environmental surfaces, especially frequently touched surfaces in patient-care areas
<b>Textiles and laundry</b>	Handle in a manner that prevents transfer of microorganisms to others and to the environment
<b>Needles and other sharps</b>	Do not recap, bend, break, or hand-manipulate used needles; if recapping is required, use a one-handed scoop technique only; use safety features when available; place used sharps in puncture-resistant container
<b>Patient resuscitation</b>	Use mouthpiece, resuscitation bag, other ventilation devices to prevent contact with mouth and oral secretions
<b>Patient placement</b>	Prioritize for single-patient room if patient is at increased risk of transmission, is likely to contaminate the environment, does not maintain appropriate hygiene, or is at increased risk of acquiring infection or developing adverse outcome following infection

(continued)

**Table 2.4.** Recommendations for application of standard precautions for the care of all patients in all healthcare settings<sup>7</sup>, continued

Component	Recommendations
<b>Respiratory hygiene/cough etiquette</b> (source containment of infectious respiratory secretions in symptomatic patients, beginning at initial point of encounter; e.g., triage and reception areas in emergency departments and physician offices)	Instruct symptomatic persons to cover mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacle; observe hand hygiene after soiling of hands with respiratory secretions; wear surgical mask if tolerated or maintain spatial separation, >3 feet if possible.

\* During aerosol-generating procedures on patients with suspected or proven infections transmitted by respiratory aerosols (e.g., SARS), wear a fit-tested N95 or higher respirator in addition to gloves, gown, and face/eye protection. As part of respiratory etiquette, EMS system responders are advised to wear an approved mask or respirator and eye protection when examining and caring for patients with signs and symptoms of a respiratory infection. More detailed information on masks is provided in the Work Practice Controls and Personal Protective Equipment (PPE) section later in the guide.

EMS system responders can adapt elements of these precautions to prevent contracting or transmitting MRSA prior to the patient's arrival to the hospital, particularly in cases in which patients have draining wounds or difficulty

controlling body fluids. Table 2.5 describes the basic components of Contact Precautions with some adaptations made for the EMS environment.

**Table 2.5.** Basic components of Contact Precautions

Component	Recommendations
<b>Patient transport</b>	Ensure infected or colonized areas of the patient's body are covered and contained; don clean PPE and perform hand hygiene prior to transporting patient and again when handling the patient upon arrival to transport destination
<b>Gloves</b>	For touching intact skin or surfaces and articles in close proximity to the patient
<b>Gown</b>	For interactions with the patient or in the patient care environment that may result in contamination of clothing or environment outside of the area of patient care; gowns should be disposed and hand hygiene performed prior to leaving the patient care environment, ensuring that clothing and skin do not come in contact with contaminated surfaces
<b>Patient care equipment</b>	When possible, use dedicated noncritical patient care equipment; ensure any nondedicated equipment is properly cleaned and disinfected before use with another patient
<b>Environmental control</b>	Develop procedures to ensure cleaning and disinfection of high-touch surfaces and areas in close proximity to patient on Contact Precautions
<b>Patient placement</b>	(Upon arrival at hospital) Single patient room, if available, or cohorting with other patients who have MRSA or who have low risk of acquiring or suffering adverse effects of a MRSA infection

Adapted from: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007. Available at: <http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>. Accessed January 24, 2013.

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1 Centers for Disease Control and Prevention. *An introduction to epidemiology*. 2004. Available at: [www.cdc.gov/excite/classroom/intro\\_epi.htm](http://www.cdc.gov/excite/classroom/intro_epi.htm). Accessed January 24, 2013.

2 Sepkowitz KA. Occupationally acquired infections in health care workers. Part I and II. *Ann Intern Med* 1996;125:826-834/917-928.

3 Implementation of Section 2695 (42 USC 300ff-131) of Public Law 111-87: Infectious Diseases and Circumstances Relevant to Notification Requirements. *Federal Register* Nov 2 2011;76(212). Available at: <http://www.cdc.gov/niosh/topics/ryanwhite/pdfs/FRN11-2-2011GPO.pdf>. Accessed January 24, 2013.

4 Centers for Disease Control and Prevention. *MRSA and the workplace*. 2011. Available at: [www.cdc.gov/niosh/topics/mrsa](http://www.cdc.gov/niosh/topics/mrsa). Accessed January 24, 2013.

5 Aureden K, Arias K, Burns L, Green, C, Hickok J, Moody J, et al. *Guide to the elimination of methicillin-resistant Staphylococcus aureus (MRSA) transmission in hospital settings*, 2nd ed. Washington, DC: Roche, 2010; 8.

6 Williams D. Danger in the station: drug resistant infections. *Fire Engineering* 2006;159:69-74.

7 The CDC Healthcare Infection Control Practices Advisory Committee. *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. Available at: <http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>. Accessed January 24, 2013.

## Additional Resources

Centers for Disease Control and Prevention. List of potentially life-threatening infectious diseases to which emergency response employees may be exposed. *Federal Register* Dec 2 2011;76(212).

NFPA 1581, Standard on Fire Department Infection Control Program, 2005.

NFPA 1582, Standard on Comprehensive Occupational Medical Program for Fire Departments, 2007.

Ryan White HIV/AIDS treatment extension act of 2009. Available at: <http://www.cdc.gov/niosh/topics/ryanwhite/>. Accessed December 13, 2012.

CDC Select Agent Program. Available at: [http://www.cdc.gov/phpr/documents/DSAT\\_brochure\\_July2011.pdf](http://www.cdc.gov/phpr/documents/DSAT_brochure_July2011.pdf). Accessed December 13, 2012.

## Section 3: Risk Factors/Risk Assessment in EMS

### Purpose

Awareness of hazards is an important part of protecting EMS system responders. Agencies can perform a hazard risk assessment to obtain a baseline incidence, prevalence, and transmission of hazards. These include exposure to communicable diseases, hazardous materials, and sharps-related injuries. The hazard risk assessment guides development of a surveillance, prevention, and infection control program.

### Key concepts

- Past and current agency-specific surveillance data is the focus of the risk assessment.
- Exposure and injury surveillance data includes demographic, geographic, and published EMS/Fire/Public Safety data on risk.
- Risk assessment should be continuously revised or updated when there is a change based on ongoing surveillance, when populations change, or when additional risks are identified.
- Information from the risk assessment drives education and improvement processes. Epidemiology is the foundation of the process.

### Background

EMS system responders face a wide variety of serious hazards due to the unpredictable nature of their jobs. There are exposure and injury risks at motor vehicle accidents, fires, hazardous materials (hazmat) incidents, and mass casualty incidents to

name a few. EMS system responders are routinely exposed to situations that threaten their personal safety, including exposures to infectious diseases, hazardous materials, and sharps-related injuries. They may encounter combative patients, patients with infectious diseases, traumatic injuries, and exposure to chemical, biological, radiological agents, and exposures related to bioterrorism.

There are many federal, state, and local practice standards, resources, and expert guidance to assist agencies with infection prevention plans. Agencies must also develop a tracking system to monitor exposure and injury trends. Monitoring trends over time will show whether incidences of exposures and sharps-related injury rates are decreasing or whether additional actions need to be taken if rates are increasing. Comparison with baseline measurements and analysis will determine the need for an intervention and determine the appropriate intervention. Continued monitoring is needed to reassess the effectiveness of the interventions.

If available, past and current agency surveillance data is the core of the risk assessment. Agencies can obtain relevant infectious disease surveillance data from local and state public health departments. Agencies should monitor community and population-specific risk factors and epidemiology for the following diseases:

- Tuberculosis
- HIV/AIDS
- Hepatitis C
- Influenza
- MRSA

- Other emerging multidrug-resistant organisms (MDROs)
- Other diseases on the CDC list of reportable diseases (see Table 2.1)

In addition, each DICO should be aware of their state's specific regulations (i.e., California 5199) for disease monitoring and reporting.

## Infectious disease and sharps injury risk factors

General risk factors for infectious diseases and sharps-related injuries are well documented in medical literature. Known risk factors include, but are not limited to:

- Exposure to patients with chronic diseases (HIV, hepatitis B and C)
- Exposure to blood and other potentially infectious fluids
- Exposure to patients with infectious diseases (MRSA, meningitis, influenza)
- Failure to use engineering controls such as self-sheathing IV catheters and needleless systems
- Failure to use appropriate sharps containers
- High-risk procedures such as intubation, IV starts, and bandaging
- Noncompliance with Standard Precautions
- Poor hand washing techniques
- Faulty, defective, or improperly used equipment
- Lack of preventative immunizations
- Failure to properly decontaminate equipment and other work surfaces
- Poorly lit work area
- Hazardous work areas including hazardous material or fire responses
- Combative patients with obvious blood exposure
- Inappropriate disposal of contaminated sharps

## Infectious diseases and sharps-related injuries risk assessment basics

EMS system responders should use Standard Precautions for all patients. They should use additional PPE based on the risks they identify from the information they receive from dispatch or from their assessment when they arrive on the scene. Some agencies have the ability to identify patients with confirmed or suspected infectious diseases in dispatch information. However, given the mobile nature of society, agencies must be aware that the person at the address may not be the same as in agency records. EMS agencies must develop relationships with hospital IPs and local public health departments to develop a system for reporting and treating personnel with exposures. The ability to track infectious disease exposures and sharps-related injuries is essential for risk assessment. Standardized processes for capturing relevant data ensure that statistical evaluation is relevant and can be compared over time. The following is an example to illustrate risk assessment basics.

The EMS exposure risk assessment requires the person responsible for tracking exposures (i.e., DICO, occupational health RN, IP) to do the following:

**Example 3.1.** Utilizing exposure surveillance data for infectious diseases, airborne, bloodborne, hazmat, and sharps-related exposures when a risk assessment is conducted

Description of exposures and action required are summarized in the table below.

EXPOSURE DESCRIPTION	ACTION REQUIRED
Exposure of open skin, cuts, or breaks or mucous membranes, such as eyes, nose, or mouth, to blood or body fluids. This includes needlesticks and human bites.	Clean exposed area; if in the mouth, rinse and spit; flush eyes as appropriate. Provide first aid if needed. Call your DICO.

**Example 3.1. Annual Summary of Reported EMS Exposures**

		Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sept.	Oct.	Nov.	Dec.	Total
	No. of exposures	1	0	2	4	4	4	2	4	2	7	2	3	35
Airborne	Infectious	0	0	1	2	2	4	1	0	1	0	1	2	14
	Hazmat	1	0	0	0	0	0	0	4	0	2	0	0	7
Bloodborne	Needlestick	0	0	0	1	0	0	0	0	0	0	0	0	1
	Nonintact skin	0	0	0	1	0	0	1	0	1	2	1	0	6
	Mucous membrane	0	0	1	0	2	0	0	0	0	3	0	1	7

- Establish baseline incidence and/or prevalence of exposures and injuries (agencies should look for the incidence rate tied to patient contacts; i.e., exposures per 1,000 patient contacts).
- Identify high-risk employee practices or stations based on incident rates and identify clusters to determine if additional interventions may be needed.
- Evaluate infectious disease transmission over time to characterize station-specific and disease-specific prevalence or transmission rates.
- Track employee absenteeism to detect subtle variances in sick leave associated with specific stations, or shifts, to serve as an early sentinel to possible infectious disease implications.
- Establish rates and ensure compliance with Standard Precautions and PPE use.
- Focus data-driven interventions on stations/employees with high exposure or injury rates.
- Obtain employee input to improve infection control policies and procedures to maximize support and participation.
- Identify gaps in knowledge for targeted educational interventions.

- Ensure employees have annual exposure control plan training that allows enough time for feedback and questions.

In the example provided, using infectious disease exposure surveillance data for the infectious disease assessment of the EMS system responders who had a reported exposure (number = 6), three were diagnosed and treated for MRSA. Since beginning to track MRSA-reported exposures, reporting has increased, although the total number of actual patients with MRSA is unknown because that information is not always given to the EMS system responder. The DICO investigated all reported MRSA-related exposure reports and determined only six patients had confirmed MRSA. Because of the Health Insurance Portability and Accountability Act (HIPAA) constraints, not all crews receive confidential patient medical information regarding their potential infectious disease status as part of the call read back from the dispatch center and hospitals do not always report back to the EMS system responders.

EMS system responders submit an exposure report and document the disease they were exposed to during patient care (see Example 3.2). EMS

**Example 3.2. MRSA exposure report**

Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of Reported MRSA Exposures	1	5	4	9	0	12	21	24



system responders are required to document the type of PPE worn. EMS agencies can analyze their exposure data to evaluate MRSA-related exposures and MRSA illness transmission to EMS system responders. This type of analysis can be done to determine crews at high risk. Interventions and education can be introduced to decrease the number of EMS system responders diagnosed with MRSA. In the case above, EMS system responders were educated on MRSA to reduce their fear of the disease and educate them on the modes of transmission.

## **MRSA assessment and intervention scenario**

As seen in Example 3.2, an upward trend of MRSA reported exposures and EMS system responders with MRSA led to increased multipronged educational interventions on how to reduce risk of contracting MRSA. This MRSA Awareness Program included:

- An interactive, visual, fact-based awareness program to crews via closed circuit TV
- Stories from actual EMS system responders (identities were kept confidential) who had contracted MRSA
- A frequently asked questions memo sent out to all crews
- CDC fact sheets sent to all crews to be posted at stations
- Reminders to crews about hand washing and use of PPE
- Reminders to crews to decontaminate all medical equipment and not to bring equipment into stations
- Quick drills sent out every 6 months to remind crews about MRSA and ways to prevent it

Agencies must continue to monitor for a reduction in MRSA-related infection rates

among EMS responders once education and infection prevention interventions have been implemented. The DICO will then communicate the results of MRSA surveillance to all employees. Employees can also be monitored for compliance with hand hygiene, use of PPE, and environmental and equipment decontamination. Although MRSA continues to be a problem in the United States, significant progress can be made among EMS system responders to reduce their risk. According to recent news broadcast (KVOA, Tucson, Arizona), Tucson Arizona Fire Department reported no cases of MRSA, which was down from 26 cases over a period of years. In 2007, the department worked with Mel and Enid College of Public Health to develop training to prevent contamination. They implemented changes such as using hand sanitizers and special cleaners, replacing fabric-covered furniture with cleanable fabric, and confining turnouts to the work area.

## **Tuberculosis risk assessment**

EMS agencies are advised to go to the CDC website to determine the tuberculosis (TB) risk for the particular area and to implement a TB elimination program. The following sites provide information to develop a TB Exposure Prevention and Skin Testing Policy:

<http://www.cdc.gov/tb/>

[http://www.cdc.gov/tb/publications/guidelines/Control\\_Elim.htm](http://www.cdc.gov/tb/publications/guidelines/Control_Elim.htm)

## **Needlestick safety and prevention act**

In response to continued problems with accidental sharps injuries, Congress passed modifications to the OSHA Bloodborne Pathogens Standard which went into effect in 2001. EMS agencies can access an easy-to-use frequently asked question guide on this topic at: <http://www.osha.gov/needlesticks/needlefaq.html>

A Needlestick-Prevention Device evaluation form can be found at: [http://www.osha.gov/OshDoc/Directive\\_pdf/CPL\\_2-2\\_69\\_APPBForm2.pdf](http://www.osha.gov/OshDoc/Directive_pdf/CPL_2-2_69_APPBForm2.pdf)

## **Resources**

Sexton J, Reynolds KA, Peate W. Study of MRSA bacteria in the fire station environment. Executive Summary, April 9, 2008.

## Section 4: Surveillance

Historically, EMS agencies have not conducted active surveillance programs. Currently there are no national benchmarks for EMS to compare infectious diseases, hazmat exposures, and sharps injuries. Each EMS agency must ensure they have a strong internal method of defining diagnosed cases or incidences and time period for each type of infectious disease, hazmat exposure, and sharps injuries that EMS system responders report.

This section presents basic surveillance methodology and an example of surveillance in EMS. For more in-depth information on surveillance, refer to chapter 3, Surveillance, in *APIC Text of Infection Control and Epidemiology*, 3rd edition (also available online at <http://text.apic.org>; subscription required to access).

### Purpose

Surveillance is an essential element of any infection prevention program.<sup>1</sup> The purpose of surveillance is to identify trends, outbreaks, emerging infectious diseases, MDROs, sharps injuries, and bioterrorism events so infection prevention measures can be implemented.

### Key concepts

- Surveillance methods continue to evolve as healthcare delivery systems shift out of traditional hospital facilities.
- A surveillance program should be designed in accordance with current practices and should consist of defined elements.
- Surveillance activities should include identifying risk factors for infection and other adverse events, implement risk-reduction activities, and monitor the effectiveness of interventions.

- Surveillance programs in EMS should include infection prevention, performance improvement, patient safety, and public health activities.

Mandatory state and federal reporting requirements frame surveillance programs.

### Components of infection prevention surveillance plan

- Select the surveillance methodology.
- Assess and define the population(s) to be studied.
- Choose the indicators (events) to monitor.
- Determine time period for observation.
- Identify surveillance criteria.
- Identify data elements to be collected.
- Determine methods for data collection and management.
- Determine methods for data analysis.
- Identify recipients of the surveillance report.
- Develop a written surveillance plan.

### Example of surveillance in EMS: Pertussis (Whooping Cough) – re-emergence of a disease in Oregon

In 2010, surveillance in Oregon led public health authorities to launch Metropolitan Area Pertussis Surveillance (MAPS), enhancing surveillance in certain counties to better delineate the epidemiology of pertussis. Each reported case was investigated extensively and standardized data was collected.

## ***Surveillance methodology***

Healthcare systems use one of three surveillance methodologies: total or whole house, targeted, or a combination of targeted and whole house. CDC surveillance requirements have moved increasingly to targeted surveillance that focuses on specific patient populations and/or specific infections, procedures, or epidemiologically significant organisms (e.g., MRSA).

In this example, targeted surveillance methodology focused on EMS system responders who were at increased risk of being exposed to pertussis. Targeted surveillance is defined and developed from the risk assessment.

## ***Population to be studied***

Targeted surveillance may focus on persons at greatest risk of adverse outcome should they become infected. In the case of pertussis surveillance in Oregon, the risk assessment determined the population to be EMS system responders who were at risk for contracting pertussis infections due to exposure from the infants and children for whom they were providing emergency care. There was increased risk of transmitting the disease to other susceptible persons, including unimmunized or incompletely immunized infants and children, including their own.

## ***Indicator monitors and time period***

Indicators are based on population served, procedures performed, and services provided. The indicator may be all EMS system responders in the workforce with a pertussis infection diagnosis.

The time period of surveillance activities is based on the needs of the organization and the scope of activities, but it must be long enough to accrue a sufficient number of cases for valid analysis. The time period may be a few months to a year.

In this case study, incidence and prevalence (below) were monitored annually.

## ***Surveillance criteria***

These must be clear, concise, and consistent so it will be comparable to historical data.

## ***Data elements***

Data elements should be determined based on the type of infection, event, or organism being monitored and the statistical elements that will be used to analyze the data. Data elements were useful in characterizing pertussis cases. Typical elements used are age, gender, diagnosis date, source patient information, culture date, culture source, and presence of known pertussis risk factors.

## ***Incidence and prevalence***

Incidence rates measure the probability that healthy people will develop a disease or sustain an injury during a specified period of time. It is the number of new cases in a population over a period of time (usually one year). Incidence tells us the rate at which new disease or injury occurs in a defined group of people with no previous record of that disease or injury.

$$\text{Incidence rate} = \frac{\text{Number of new cases over a period of time}}{\text{Population at risk}}$$

Prevalence rates measure the number of people in a population who have the disease or injury at a given time. Prevalence depends on the number of people who have been ill in the past and duration of the illness. A prevalence rate will include all new incidence of the disease at the time it is measured. Therefore prevalence includes both new and existing cases.

$$\text{Prevalence rate} = \frac{\text{Number of existing cases at a point in time}}{\text{Total population}}$$

When using incidence rates, the population at risk is that subset of the total population that is specifically at risk for developing a disease or sustaining an injury.

In the pertussis example, the surveillance data revealed that cases of pertussis in Oregon had tripled in number from the same time the previous year. In the fall of 2011 when the Portland fire and rescue department first began to see the number of pertussis cases rise in nearby Washington state and in Oregon, the department proactively offered all firefighters the tetanus, diphtheria, and acellular pertussis (Tdap) vaccination. Because cases of pertussis occur in adults because of decline in protective immunity over time, the Tdap vaccine would not only protect the firefighters themselves, but it would also help protect their families and high-risk children and infants to which they provide care. Although there was an increase in the number of pertussis cases in the general population, no firefighters have reported contracting pertussis since the Tdap vaccine was offered.

CDC now requires all EMS system providers who have not previously received the Tdap vaccine as an adult, and who have direct patient contact, to receive a single dose of Tdap to protect EMS system providers and their patients against pertussis. Tdap can be administered regardless of interval since the previous tetanus-diphtheria (Td) dose; however, shorter intervals between Tdap and Td may increase the risk of mild local reaction at injection site.<sup>2</sup> EMS agencies can purchase Tdap vaccine through their local health departments. For more information related to this requirement, Tdap consent and declination forms go to: <http://www.cdc.gov/vaccines/who/teens/vaccines/tdap.html>

### ***Surveillance data analysis and management***

Before initiating data collection, it is important to determine the statistical measures that will be used in data analysis. If rates or ratios will be calculated, the values corresponding to each numerator and denominator must be defined.

At this time, EMS surveillance is not as sophisticated as hospital-based surveillance. EMS systems across the United States may track the number of cases of EMS responders diagnosed with pertussis; however, there is no comparison of data across agencies. An agency could track and report pertussis incidents and rates using a standardized definition, such as:

New pertussis case = pertussis-positive diagnosis from EMS responder with new onset history of pertussis divided by the number of EMS responders in the study population in a particular time period.

### ***Written surveillance plan***

A written surveillance plan should describe the objectives, the indicators (monitors), the reason for selecting each indicator, the methodology used for case identification, data collection, analysis, and the type of reports generated. The surveillance plan should be developed to address the specifics of the organization.

### ***Surveillance program evaluation***

The surveillance program should be evaluated at least annually to determine trends and the efficacy of actions, as well as its usefulness and ability to meet the organization's objectives. Revisions should be made at time of review, or sooner when indicated by ongoing surveillance results if changes in incidence or outbreaks are identified. If an outbreak occurs or incidences of a certain disease increases, action should be taken immediately to meet the organization's stated objectives.

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## Additional Resources

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## Section 5: Engineering and Work Practice Controls and Personal Protective Equipment

### Purpose

Engineering and work practice controls and PPE are key components to a comprehensive infection prevention program. They maximize protection against infectious diseases and sharps-related injuries for both EMS system responders and the public. The term engineering controls addresses redesign of equipment to ensure employee risk reduction, procedures that serve to reduce exposure such as cleaning equipment or areas that have been contaminated, and the use of barrier techniques to reduce direct contact with blood and other potentially infectious materials.

### Key concepts

- Hand washing is the single most important means of preventing the spread of disease (see example of proper hand hygiene at the end of this section).
- Risk of exposure to infectious diseases and sharps-related injuries can be greatly reduced and eliminated by introducing and adhering to best practices and the Needlestick Safety and Prevention Act of 2000 for engineering and workplace controls.
- The word “personal” in PPE means EMS system responders are responsible to wear PPE for their own personal safety. Supervisors and DICOs are responsible to ensure their employees are adhering to policies.
- The use of Standard Precautions and utilizing PPE for all patient contact is

recommended to minimize infectious disease transmission to EMS system responders.

- Any body fluid containing **visible blood** and other potentially infectious materials (OPIM) pose increased risk. OPIM include the following:
  - Cerebrospinal fluid
  - Synovial fluid
  - Amniotic fluid
  - Pericardial fluid
  - Vaginal secretions
  - Semen
- Effective environmental cleaning, disinfection, and disposal of contaminated materials or equipment will reduce the risk of infectious disease transmission.

### Background

The U.S. Department of Labor estimates there are approximately 1.5 million EMS personnel and firefighters (many of whom are crossed trained in EMS) and 794,300 police and detectives along with 493,100 correctional officers who are at risk for being exposed to infectious diseases and sharps-related injuries.<sup>1</sup> EMS system responders and their patients face a growing number of exposures to infectious diseases including MDROs. Self-protection from infection includes cleaning and disinfecting ambulances, fire apparatus, patrol cars, and equipment. In order to prevent infectious disease exposures there must be an emphasis placed on the commitment



to establishing an organizational culture that encourages the proper use of PPE and adherence to policies and procedures. This chapter details methods EMS system responders can utilize to maintain a clean, safe work environment.

## Standard Precautions

Standard Precautions are based on the principle that all blood, body fluid secretions, excretions (except sweat), nonintact skin, and mucous membranes may contain infectious organisms. Implementation of Standard Precautions is the primary strategy preventing healthcare-associated transmission of infectious agents among patients and healthcare personnel.<sup>2</sup> Standard Precautions are intended to be applied to the care of all patients in EMS and healthcare settings. These practices include: hand hygiene, use of PPE (gloves, gown, mask, eye protection or face shield, depending on the anticipated exposure), and safe injection practices. See Table 2.4 in Section 2 for an overview of Standard Precautions components.

PPE can prevent blood and other body fluids from coming in contact with skin, eyes, and mouth.<sup>3</sup> Equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a way that prevents transmission of infectious agents (e.g., wear gloves for handling soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient, ensure the appropriate disposal of contaminated disposable items).

The application of Standard Precautions during patient care is determined by the nature of the emergency responder–patient interaction and the extent of anticipated blood, body fluid, or pathogen exposure. For some patient care, such as starting an IV, only gloves may be needed. When a patient is being intubated the use of gloves and face shield or mask and goggles are required. OSHA requires a chart that lists tasks and PPE to be used when performing tasks (see page 51).

Another mode of disease transmission is respiratory (e.g., cough, congestion, or droplets from the nose). Respiratory/cough etiquette recommendations are intended to decrease the spread of infectious particles that are expelled via respiratory droplets. There are four primary components: education, source control, hand hygiene, and spatial separation.

EMS system responders are advised to wear a mask, gloves, and eye protection when examining and caring for patients with signs and symptoms of a respiratory infection, fever, or flu-like symptoms (temperature range 100°F or greater, runny nose, cough, sneezing, and bodily aches). They must take precautions by covering the mouth and nose of a potentially infectious patient with a tissue when the patient is coughing, properly disposing of used tissues, using a surgical mask on the coughing patient when tolerated and appropriate, and washing their hands after contact with respiratory secretions or droplets. To minimize the risk of respiratory transmitted infection, it is advisable to keep a safe distance (if possible, at least 6 feet) from the patient.<sup>4</sup> Minimize the number of crew members caring for the patient and within the breathing/coughing zone of the patient.

The CDC's Public Health Guidance for Community Level Preparedness and Response to Severe Acute Respiratory Syndrome (SARS)<sup>5</sup> recommends the receiving facility staff meet the patient at the ambulance door to limit the need for EMS system responders to enter the emergency department in contaminated PPE. After transferring the patient, the EMS system responder should remove and discard their PPE and perform hand hygiene. This can be done for other types of infectious diseases other than SARS. These simple measures are very important during an infectious disease disaster. A 2004 study found that 40 percent of healthcare personnel who developed SARS after exposures to coughing patients had not been wearing a mask or eye protection when exposed. Many, if not all of these

infections may have been prevented if healthcare personnel had been wearing respiratory and eye protection.

Hand hygiene is also an important component of respiratory etiquette and critical response to an infectious disease disaster. Education about hand hygiene should improve knowledge and reinforce positive behavior.<sup>6</sup>

## **Defining engineering and work practice controls**

Engineering controls are devices or changes in the physical environment that reduce the risk of exposure. These are important to isolate or remove the infectious disease hazards from the workplace. Examples of these are self-sheathing IV catheters, needleless systems, puncture-proof containers, decontamination areas, masks, respirators, and adequate ventilation systems.

EMS agencies need to conduct periodic surveys to evaluate the use of engineering controls and identify current needs. The process should include the ability to conduct appropriate evaluations and/or field tests to ensure the devices will not adversely impact the delivery of patient care or result in providers delaying treatment attempting to circumvent the intended functioning of the safety device. Determine whether there should be adjustments to the system's protocols, clinical operating guidelines, and educational requirements to integrate use of devices into the patient care system.

Work practice controls are behavior-based and are intended to reduce the risk of exposure by changing the way in which the tasks are performed. Examples of these are avoiding passing a syringe with an unsheathed needle and placing sharps directly into appropriate sharps containers located as closely to the point of care as possible. EMS system responders have been reported to stick a needle in their boot, stretcher mattress, bench seat, and box of gloves because they stated

they did not have a chance to grab a sharps container. These methods are not acceptable and pose increased risk of needlesticks to the individual, his or her colleagues, and the patient.

## **Basic engineering control components**

The following engineering controls should be in use at each station or apparatus:

- Hand washing facilities
- Availability of alcohol-based hand cleansers or towelettes for on-scene use
- Disinfectant wipes for equipment
- Self-sheathing IV catheters and needleless systems
- Puncture-resistant, leak-proof, color-coded, conveniently located sharps containers that are available on response apparatus
- Leak-proof, properly labeled, and conveniently located contaminated-waste receptacles
- Decontamination areas at stations (see page 34 for description)
- Single-use devices in place of reusable devices

The Federal Needlestick Safety and Prevention Act provides additional guidance on sharps injury prevention.<sup>7</sup>

All EMS system responders that have rotating or changing assignments should be oriented to the engineering controls in the station or apparatus by a designated and knowledgeable person.

## **Basic work practice controls**

The following work practice controls must be used by all personnel:

- Wash hands or use antiseptic hand cleaner<sup>8</sup> before and after patient care,

before and as soon as gloves are removed, on returning to the station, after cleaning or decontaminating equipment, after using the restroom, and before preparing food.

- Flush eyes or mucous membranes with large amounts of water or saline if exposed to blood or body fluids.
- Dispose of sharps in puncture-resistant containers and keep in a secure position.
- Do not eat, drink, smoke, or handle contact lenses or apply lip balm in areas of possible contamination (in emergency vehicles, on scene, or while cleaning equipment).
- Use pocket masks or bag valve masks for ventilation.
- Do not keep food and drink in refrigerators designated biohazard with potentially infectious materials or medications.
- Place blood specimens in marked plastic bags for transport.
- Dispose of sharps containers when three-quarters full or when at the full line.
- Appropriate identification and disposition of medical waste according to state regulations.

## **Personal protective equipment**

PPE is barrier protection and the last line of defense to prevent occupational exposure to blood or body fluids. PPE is necessary because all exposures cannot be minimized or eliminated by engineering or work practice controls. PPE reduces the risk but is only effective if used correctly. The use of PPE does not replace basic hygiene measures. Hand washing is still essential to prevent transmission of infection.

Appropriate use of gloves helps protect both EMS system responders and patients from exposures to infectious diseases. Nonsterile disposable medical gloves should be available to all EMS system

responders. Gloves manufactured for healthcare purposes are subject to U.S. Food and Drug Administration (FDA) evaluation and clearance.<sup>9</sup> Gloves are available in vinyl, nitrile, and latex. If possible, avoid use of latex and nitrile gloves due to latex sensitivity in personnel and patients and documented problems with nitrile gloves. Due to the sometimes dangerous conditions under which EMS system responders have to provide patient care (i.e., motor vehicle accidents), it is highly recommended to use an alternative, more durable type glove and/or use a double gloving routine. If fire-fighting gloves are worn over medical gloves, wash them with disinfectant detergent upon returning to the station or according to manufacturer's instructions.

Masks can protect EMS system responders from infectious diseases, respiratory exposures, and splashes of blood and other body fluids. States vary on their mask requirements. Check state rules. Departments required to use masks should provide personnel with well-fitting surgical/medical or N95 respirators. If employers choose the NIOSH-approved N95 respirator they are required by OSHA to conduct an initial medical clearance, provide fit testing (respirator fit testing performed to determine if an employee can maintain an acceptable respiratory fit and seal), education on proper use, and conduct periodic (annual at a minimum) re-evaluation.<sup>10</sup>

Goggles or safety glasses for eye protection should be issued. They should fit comfortably and securely and allow for peripheral vision. EMS system responders can also use prescription glasses with removable side shields per OSHA. These protect from splashes and respiratory diseases spread by droplets.

When exposure to large amounts of blood or body fluid is anticipated, the use of a gown, sleeves, or booties over boots is also recommended.

The employer is responsible for the supply, repair, replacement, and safe disposal of contaminated PPE. EMS system responders must report any

issues with PPE verbally and in writing to their manager. Reusable PPE should be cleaned after every use or as needed. The following guidelines should be followed when using PPE:

- Discard all disposable contaminated PPE in appropriate containers as soon as feasible. Follow your state rules for discarding contaminated PPE.
- Remove and appropriately dispose of gloves when they become soiled or torn.

EMS system responders, including police and correctional officers, should carry an extra change of work clothing with them at all times in the event their work clothes are grossly contaminated in the course of their work.

Although there are no known documented transmissions of HBV or HIV during mouth-to-mouth resuscitation, due to the risk of salivary transmission of other infectious diseases (e.g., herpes simplex, *Neisseria meningitidis*), disposable airway equipment or resuscitation bags should be used during artificial ventilation. Disposable equipment is preferred but if multiuse equipment is used, follow the manufacturer's recommendations for cleaning and disinfection.

## **Law enforcement and correctional facility officers**

Officers may face the risk of exposures to blood during the conduct of their duties. They may encounter blood-contaminated hypodermic needles or weapons or be called upon to assist with body removal. In order to reduce risk, the following guidelines should be followed<sup>11</sup>:

- When blood is present and a suspect or inmate is combative or threatening to staff, gloves should be put on as soon as conditions permit.
- Protective masks or airways should be easily accessible in case mouth-to-mouth is needed.

- Due to the risk of puncture wounds or needlesticks during suspect searches, an officer should use extreme caution in searching the clothing of suspects. Wear protective gloves, especially for body searches.
- Always use a flashlight to search such areas as under the seat of a car or purse to avoid being stuck.
- To avoid tearing gloves, use evidence tape instead of staples to seal evidence.
- Use puncture-proof containers to store sharp instruments.
- Use thick gloves to search suspects.
- Avoid handling personal items while wearing contaminated gloves.
- Prisoners may spit at officers and throw feces; sometimes these substances have been purposefully contaminated with blood. Although there are no documented cases of HBV or HIV transmission from this, other diseases could be transmitted. These materials should be removed after donning gloves then decontaminate with an appropriate germicide and dispose of gloves properly.

## **Environmental decontamination**

### ***General principles of disinfection***

The rationale for cleaning, disinfecting, or sterilizing patient care equipment can be understood more readily if medical devices, equipment, and surgical materials are divided into three general categories based on the potential risk of infection involved in their use: critical items, semicritical items, and noncritical items.

Critical items are instruments such as needles or surgical instruments that are introduced directly into the bloodstream or into other normally sterile areas of the body. These items are sterile at the time of use.

Semicritical items are items such as laryngoscope blades, Magill forceps, and other items that may come in contact with mucous membranes but do not ordinarily penetrate body surfaces. Although sterilization is preferred for these instruments, a high-level disinfecting procedure that destroys microorganisms, most fungal spores, tubercle bacilli, and small nonlipid viruses may be used after meticulous physical cleaning to remove any visible contamination.

Noncritical items either do not ordinarily touch the patient or touch only intact skin.

Items include splints, backboards, and blood pressure cuffs. Disinfect noncritical items by cleaning with soap and water followed by disinfection with an appropriate disinfectant. Equipment must be thoroughly cleaned with soap and water and scrubbed to remove organic matter (blood and tissue) and other residue. Cleaning must precede disinfection because organic matter shields organisms from destruction and may inactivate some disinfectants. Scrubbing to remove gross decontamination is more effective than soaking because soaking does not always remove all contaminants.

## **Disinfection procedures**

### ***General procedure***

Upon the completion of all responses, contaminated equipment should be removed and replaced with clean equipment. Supplies of PPE on response vehicles should also be restocked. Contaminated equipment should be placed in a leak-proof bag and segregated from clean equipment. Cleaning and decontamination should be done as soon as practical.

Utility gloves should be worn when cleaning equipment and when using disinfectants to protect the skin from damage and contamination. OSHA states that the employer should base the selection of appropriate hand protection on an evaluation of the performance characteristics of

the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.<sup>9</sup>

Wash hands and change clothes, if necessary, after decontamination of equipment and clothing. Before disinfection, equipment must be thoroughly cleaned with soap and water and scrubbed to remove organic matter (blood and tissue) and other residue.

Ensure cleaned items are properly stored to prevent reinfection or contamination during storage.

### ***Disinfection solutions***

Select U.S. Environmental Protection Agency (EPA)-registered disinfectants or detergent/disinfectants that meet the department's routine cleaning and disinfection guidelines.<sup>12</sup> Follow manufacturer's guidelines for appropriate selection and use of disinfecting solutions, and pay special attention to the prescribed contact time.

### ***Decontamination stations***

Each station is required by OSHA to have a decontamination area. These areas should be marked with decontamination area and biohazard signs and symbols and equipped with the following:

- A sink, constructed of nonporous materials with proper lighting
- Adequate counter areas constructed of nonporous materials with rack space to allow air-drying of equipment
- Appropriate containers for disposal of biohazard waste (receptacles/red bags)
- Facilities for the safe storage, use, and disposal of cleansing and disinfecting solutions along with appropriate PPE (safety glasses/goggles, utility gloves, face masks)
- Material safety data sheets (MSDSs) for cleaning and disinfecting solutions. MSDS information may be kept

electronically; however, they must be accessible to all employees and updated as new products are purchased

- Liquid soap and paper towels
- Sharps container

All EMS system responders using these solutions should be familiar with the MSDS and should use the recommended PPE. **Under no circumstances should kitchens, bathrooms, or living areas be used for decontamination or storage of patient care equipment or infectious waste.**

### ***Equipment decontamination***

#### **1. Semicritical items such as laryngoscopes, Magill forceps, and bag mask ventilation devices:**

Clean and scrub with soap and water, paying attention to crevices. Soak in disinfectant per manufacturer's instructions. Thoroughly rinse equipment several times with copious amounts of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment manufacturer.

#### **2. Delicate equipment such as cardiac monitors, defibrillators, glucometers, and radios:**

Clean with soap and warm water and wipe or spray with disinfectant. Do not spray disinfectant on the screen or controls of the monitors or defibrillators. Use disinfectants or ready-to-use disinfectant wipes on paddles and wires.

**3. Patient transport equipment such as backboards, extrication devices, etc.:** Clean and scrub with soap and warm water, paying attention to crevices, and wipe or spray with appropriate disinfectant and allow equipment to air-dry.

**4. Medical/Trauma/Pediatric Kits:** Empty contents weekly and wash kit with soap and water. Wipe or spray with disinfectant, and let air-dry.

**5. Emergency Apparatus (engines, trucks, rescues, patrol vehicles):** Exterior and interior surfaces of vehicles, especially those areas

that are commonly handled by EMS system responders (e.g., door handles, steering wheel, clipboard, etc.), should be disinfected at least weekly and after each call where the potential for contamination exists. Wipe with soap and water then wipe or spray with disinfectant and allow a 1 minute contact time (air-dry).<sup>13</sup>

**6. Miscellaneous equipment** such as stethoscopes, thermometers, blood pressure cuffs, instrument cases, sharps containers: These items should be disinfected weekly and after each call where potential for contamination exists. Wipe with soap and water and then wipe or spray with disinfectant and let air-dry. When contamination of shoes worn on calls is suspected, shoes should be cleaned with soap and water before entering living quarters.

**7. Stations/Living quarters:** Recent research shows increased rates of MRSA in fire stations, ambulances, and fire apparatuses.<sup>14</sup> Crews must clean or disinfect their equipment and items inside their stations to include counters, door handles, remote controls, sinks, furniture, exercise equipment, and any other shared use items. An appropriate disinfectant or a 1:100 (1 part bleach to 99 parts of water) concentration of water to household bleach can be used to clean most surfaces. The bleach solution should always be made just prior to its use to ensure effectiveness.<sup>15</sup>

**8. Soiled or contaminated uniforms, bunker gear, turnouts:** Wash immediately with detergent. Contaminated bunker gear/turnouts should be cleaned according to the manufacturer's recommendation and National Fire Protection Association (NFPA) 1581.

**9. Boots and shoes:** When there is a massive amount of blood contamination on floors, the use of disposable impervious shoe coverings should be considered. Boots and leather goods may be brush scrubbed with soap and water to remove contamination.

10. **Oxygen tanks:** Spent oxygen tanks should be visibly inspected and cleaned/disinfected if they are contaminated with blood or OPIM.

### ***Blood and body fluid spills***

Use layered disposable superabsorbent pads on large amounts of blood. Wearing proper PPE, place the needed number of pads over the liquid. Liquid will be absorbed quickly into the pad for safer handling. Carefully pick up the pad and place in red biohazard bag. Use disinfectant and apply over the affected area and, if needed, rinse the affected area with a small amount of water.

### ***Skin and mucous membranes***

Any intact skin contamination to blood or body fluids should be removed by washing with soap and water. Vigorously wash the affected area for a minimum of 15 seconds. Examine exposed skin for any breaks or rough chapped areas. Any nonintact skin should be covered with a dressing directed by OSHA. If the area is too large, personnel should be placed on restricted duty until their wound heals. Do not use strong chemical solutions like bleach or an approved disinfectant solution to disinfect skin as they can cause skin irritation and allergic problems. Any mucous membrane exposure to blood or body fluids should be decontaminated by rinsing with large amounts of water or saline solution. Rinse the affected area for 2 minutes. Eyes may be irrigated using large amounts of water. Rinse the affected eye(s) for 3 minutes. If this is not available, saline solution and IV tubing may be used.

### ***Disposal of contaminated items***

Disposable equipment and other waste generated during on-scene operations should be discarded into an appropriate waste container. Used needles and other sharps should be disposed of in approved sharps containers. Sharps containers should be easily accessible on scene. Blood, suctioned fluids, or other liquid waste may be poured carefully into a drain connected to a

sanitary sewer system. Self-contained suction canisters should be recapped and placed in a sealable plastic bag to prevent leakage of the contained items.

### ***Ambulance and rescues***

These vehicles are mobile patient care environments. Air circulation in the vehicle is generally rapid, low-velocity airflow. Some ventilation systems fully exchange patient care air space in 1 to 2 minutes. Some vehicles have high-efficiency particulate air (HEPA) filters which need to be changed every 6 months. There are also exhaust fans to assist in air exchange. These air handling systems allow for good ventilation. However, if a patient is exhibiting the signs of a respiratory disease such as presented earlier in the guide, place a mask or tissue over their mouth as tolerated.

The ambulance cab should be maintained as a “clean zone,” free of contamination. Gloves or other PPE used during patient care should be removed prior to entering the cab. Grossly contaminated clothing should also be removed before entering the cab and place the clothes in an appropriate dirty or contaminated linen bag as marked.

The ambulance cab should be promptly decontaminated with detergent or disinfectant at the earliest practical opportunity following contamination.

A detailed ambulance cleaning procedure can be found in Appendix A.

### ***Emerging technologies***

With the increase in community-associated infections and threats of contamination of EMS system responders, systems continue to be developed to disinfect EMS vehicles.

Recently approved by CDC for hospital room disinfection, “fogging” systems previously tested and used in stationary medical units such as hospitals may hold promise for disinfecting EMS




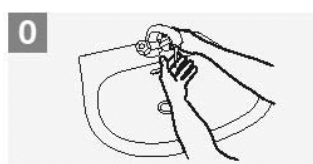
vehicles. Research on the use of this technology in EMS needs to be performed. Most of these systems utilize an alcohol-based chemical that is able to penetrate ventilation ducts, under equipment, and in various cracks and crevices often missed during routine manual sanitizing.

Additional technologies, chemicals, and systems continue to be explored and tested in order to improve vehicle decontamination. It is mandatory that whenever any cleaning product is added to a department's chemical inventory, even products under trial use, that the MSDS is added

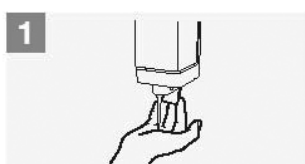
# How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

 Duration of the entire procedure: 40-60 seconds



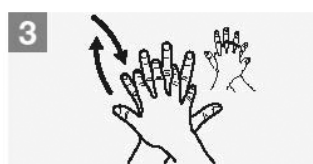
Wet hands with water;



Apply enough soap to cover all hand surfaces;



Rub hands palm to palm;



Right palm over left dorsum with interlaced fingers and vice versa;



Palm to palm with fingers interlaced;



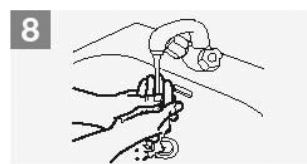
Backs of fingers to opposing palms with fingers interlocked;



Rotational rubbing of left thumb clasped in right palm and vice versa;



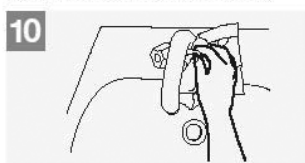
Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



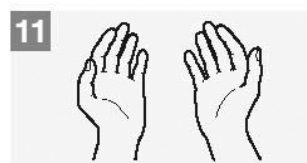
Rinse hands with water;



Dry hands thoroughly with a single use towel;



Use towel to turn off faucet;



Your hands are now safe.



World Health  
Organization

Patient Safety  
A World Alliance for Safer Health Care

SAVE LIVES  
Clean Your Hands

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May 2009

Source: <http://www.cdc.gov/handhygiene/Basics.html>

to the department's electronic MSDS inventory and printed for inclusion in the paper MSDS inventory. All secondary containers (spray/squirt bottles) for the dispensing of disinfection solutions need to be labeled with the appropriate contents.

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## Additional Resources

Standard on Fire Department Infection Control Program. National Fire Protection Association, (NFPA) 1581. Available at: <http://www.nfpa.org/AboutTheCodes/AboutTheCodes.asp?docnum=1581&tab=docinfo>

## **Guide to Infection Prevention in Emergency Medical Services**

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Needlestick Safety and Prevention Act. [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_cong\\_public\\_laws&docid=f:publ430.106](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ430.106)

OSHA Bloodborne Pathogen Standard. [http://www.osha.gov/SLTC/bloodbornepathogens/gen\\_guidance.html](http://www.osha.gov/SLTC/bloodbornepathogens/gen_guidance.html)

OSHA Enforcement Procedures for the Occupational Exposure. [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=DIRECTIVES&p\\_id=2570](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570)

## Section 6: Occupational Exposure Health Issues

### Purpose

Anyone whose job requires providing EMS system response medical care in which there is a reasonable expectation of contact with blood or OPIM is at risk for contracting an infectious disease.<sup>1, 2</sup> Communication, collaboration, planning, and using PPE can prevent and/or mitigate, to a great extent, the outcomes of such exposures. This chapter identifies infection risks and possible solutions.

### Key concepts

- EMS agencies need to provide a safe environment for their staff.
- The DICO has a vital role in identifying the risks associated with the work of EMS system responders.
- EMS system responders need to understand that exposure does not necessarily mean they have been infected.
- An Exposure Control Plan (ECP) must include more than just information on bloodborne pathogens, and this information must be understood by all employees.
- Management must support and provide the resources for appropriate implementation of the ECP in order for it to be effective.
- Adequate and timely communication across healthcare settings helps address the unique infection transmission risks experienced by EMS system responders.<sup>3</sup>

Agencies may internally delegate infection issues to a DICO to focus more attention on infection prevention. The DICO must receive specialized training and be knowledgeable on infection prevention. This is consistent with the Ryan White Act and the National Fire Protection Standard 1581 for handling exposure incidents. Prior collaboration between local hospitals, DICOs, and those who interact with the potentially infected patient will enhance a timely response, if an employee is exposed. Some jurisdictions may rely solely on the Ryan White Act which now includes a clause that requires the notification of EMS system responders (this includes law enforcement and corrections officers) if a patient with which they worked is determined to be infectious. IPs at all medical facilities must be familiar with this law and their facility's protocol in meeting its strict time requirements. Collaboration between public health, medical facilities, and DCIO/IPs from involved agencies must be ongoing.

### Bloodborne pathogen exposure control plan

An understandable, functional, written ECP that is used daily is crucial to the success of your program and safety of your employees. (See Appendix B for a sample Exposure Control Plan.) All of the requirements of OSHA's Bloodborne Pathogens standard can be found in Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030. States and territories that operate their own OSHA-approved state programs are required to adopt a bloodborne pathogens standard that is

at least as effective as the federal OSHA standard.<sup>4</sup> If you are implementing a new program, check state and federal authorities to see whose jurisdiction your organization must follow.

Public employees in non-OSHA participating states may fall under different state regulations (or none). However, the plan outlined is a minimum standard and should be noted.

The OSHA standard requires the following nine elements as the foundation of a Bloodborne Pathogen program (for a Quick Reference Guide to the Bloodborne Pathogens Standard, see [http://www.osha.gov/SLTC/bloodbornepathogens/bloodborne\\_quickref.html](http://www.osha.gov/SLTC/bloodbornepathogens/bloodborne_quickref.html)).

1. **Determination of employee exposure**

The employer must create a list of job classifications in which all workers have occupational exposure and a list of job classifications in which some workers have occupational exposure, along with a list of the tasks and procedures performed by those workers that result in their exposure. This list also determines who needs ECP training. See Example 6.1 at the end of this section for an example of a job classification list for fire departments.

2. **Implementation, including date, of various methods of exposure control including:**

- *Standard Precautions:* One must treat all human blood and OPIM as if known to be infectious for bloodborne pathogens.
- *Engineering and work practice controls:* Identify and use engineering controls. Identify and ensure the use of work practice controls. You should already have safer devices in place. If you have not already evaluated and implemented appropriate and available engineering controls, you must do so now. Also, employees with

occupational exposure to blood and OPIM must be trained regarding the proper use of all engineering and work practice controls.

- *Personal protective equipment (PPE):* Provide PPE such as gloves, gowns, eye protection, and masks. Employees must clean, repair, and replace this equipment as needed. Provision, maintenance, repair, and replacement are at no cost to the employee.

3. **Hepatitis B vaccination**

This vaccination must be offered after the worker has received the required bloodborne pathogens training and within 10 days of initial assignment to a job with occupational exposure. Written documentation must be kept if the worker declines to be vaccinated.

4. **Postexposure evaluation and follow-up**

Make available a postexposure evaluation and follow-up for any worker who experiences an occupational exposure incident. This should be done immediately as postexposure prophylactic medications, if needed, should be started within a few hours.

*Procedures for evaluating circumstances surrounding exposure incidents*

- An exposure incident is a specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or OPIM that results from the performance of an EMS system responder's duties.
- The evaluation and follow-up must be at no cost to the worker and includes documenting the route(s) of exposure and the circumstances under which the exposure incident occurred.
  - Identifying and testing the source individual for HBV, HCV, syphilis, and HIV infectivity, if the source individual consents or the law does not require consent;

rapid HIV testing is enforced by OSHA

- Collecting and testing the exposed worker's blood, if the worker consents (for baseline)
- Offering postexposure prophylaxis
- Offering counseling and evaluating reported illnesses
- The healthcare personnel will provide a limited written opinion to the employer and all diagnoses must remain confidential

**5. Communication of hazards to employees**

Warning labels must be affixed to containers of regulated waste, containers of contaminated sharps, contaminated equipment that is being shipped or serviced, and bags or containers of contaminated laundry, except as provided in the standard.<sup>5</sup>

**6. Provide information and training to workers**

Employers must ensure that their workers receive regular training that covers all elements of the standard.<sup>6</sup> Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Annual training differs from initial training. Workers must have the opportunity to ask the trainer questions. Training must be presented at an educational level and in a language that workers understand.

**7. Recordkeeping**

Medical records relating to exposures must be kept for 30 years beyond the time of employment. Training records must be kept for 3 years. The employer also must maintain a Sharps Injury Log, unless it is exempt under Part 1904 — Recording and Reporting Occupational

Injuries and Illnesses, in Title 29 of the Code of Federal Regulations.

**8. Creation of a written plan, updated annually**

The update must reflect changes in tasks, procedures, and positions that affect occupational exposure, and technological changes that eliminate or reduce occupational exposure. In addition, employers must annually document in the plan that they have considered and begun using appropriate, commercially available, effective, safer medical devices designed to eliminate or minimize occupational exposure. Employers must also document that they have solicited input from frontline workers in identifying, evaluating, and selecting effective engineering and work practice controls.

**9. Infectious diseases prevalent in your area**

Another element of an ECP should include the infectious diseases prevalent in your area. Collaborate and interact with your local health department to gather this information. Many states post this information online. You can also conduct a risk assessment to determine which diseases to target. The lists included in the Ryan White Act are a good starting point. Signs and symptoms as well as prevention methods should be discussed and updated annually.

Even with your ECP and all the safety nets in place, there are going to be times when gloves tear, clothes over nonintact skin get soaked with blood, or a coughing patient sprays an unprotected face. This is when planning comes to fruition, as demonstrated by the case study presented here.

## Case Study

During a search of a suspect in custody, a law enforcement officer is stuck deeply by a recently

used, uncapped heroin syringe. In line with the Police Agency's Exposure Control Plan they contact the agency DICO/IP who triages the situation, advises that the officer needs to report to the local emergency room, with the suspect, for a source blood draw. The IP reminds the officer that their immunization record indicates a Tdap 4 years ago and a post-HBV series titer >150 mIU/mL (anything  $\geq 10$  mIU/mL is protective against HBV acquisition; testing the suspect for HBV is not necessary). The suspect consents to HIV, HCV, and syphilis testing and is found to be HIV positive and HCV negative after testing. The syphilis lab is pending. The cost of the suspect's testing is part of the officer's workers' compensation case. The officer has baseline labs drawn, is counseled, and given the first dose of postexposure prophylactic antiviral medications within the first several hours following exposure. The officer will receive follow-up with labs and counseling. The hospital IP calls the agency DCIO/IP the next day with the syphilis results. With preexisting relationships among providers, the facility IP, and agency DICO/IP, appropriate service was provided in a timely fashion. Note: this situation also calls for an entry on the agency's sharps log, even though the type of device is listed as unknown. Some risk mitigation with the officer would be to discuss the inherent exposure risk and encourage the use of Kevlar gloves during pat downs.

## **The Ryan White Act**

The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111-87) addresses notification procedures and requirements for medical facilities and state public health officers and their designated officers regarding exposure of emergency response employees (EREs) to potentially life-threatening infectious diseases.<sup>5</sup> The Ryan White Act identifies other infectious diseases of concern.<sup>6</sup> The list of potentially life-threatening infectious diseases to which EMS system responders may be exposed was presented previously in this guide. These diseases include those caused by any transmissible agent included

in the Department of Health and Human Services (HHS) Select Agents List. Many are not routinely transmitted human to human but may be transmitted by exposure to contaminated environments. The HHS Select Agents List is updated regularly and can be found on the National Select Agent Registry website: <http://www.selectagents.gov/>. See Example 6.2 for a list of Select Agents as of December 5, 2012.

The Ryan White Act specifies that medical facilities must respond to appropriate requests by making determinations about whether EMS system responder's have been exposed to infectious diseases as soon as possible but no longer than 48 hours.

A medical facility has access to two types of information related to a potential exposure incident to use in making a determination.

First, the DICO's request submitted to the medical facility contains a "statement of the facts collected" about the EMS system responder's potential exposure incident. Information about infectious disease transmission provided in relevant CDC guidance documents<sup>7, 8, 9</sup> or in current medical literature should be considered in assessing whether there is a realistic possibility that the exposure incident described in the statement of the facts could potentially transmit an infectious disease.

Second, the medical facility possesses medical information about the victim of an emergency transported and/or treated by the EMS system responder. This is the medical information that the medical facility would normally obtain according to its usual standards of care to diagnose or treat the victim, since the Act does not require special testing in response to a request for a determination. Each state varies in their consent and testing requirements so check with your state or local health department to determine your process.

Information about the potential exposure incident and medical information about the victim



should be used to make one of four possible determinations (see <http://www.cdc.gov/niosh/topics/ryanwhite/> for easy-to-follow flow charts with procedures for notification of possible exposure to infectious diseases).

1. **The EMS system responder involved has been exposed to an infectious disease included on the list.**

Facts provided in the request document a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved EMS system responder; and the medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved EMS system responder had a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

2. **The EMS system responder involved has not been exposed to an infectious disease included on the list.**

Facts provided in the request rule out a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved EMS system responder; or the medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved EMS system responder did not have a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

3. **The medical facility possesses no information on whether the victim involved has an infectious disease included on the list.**

The medical facility lacks sufficient medical information allowing it to

determine whether the victim of an emergency treated and/or transported by the involved EMS system responder had, or did not have, a listed infectious disease at the time of the potential exposure incident.

If the medical facility subsequently acquires sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved EMS system responder had a listed infectious disease that was possibly contagious at the time of the potential exposure incident, then it should revise its determination to reflect the new information.

4. **The facts submitted in the request are insufficient to make the determination about whether the EMS system responder was exposed to an infectious disease included on the list.**

Facts provided in the request insufficiently document the exposure incident, making it impossible to determine if there was a realistic possibility that an exposure incident occurred with potential for transmitting an infectious disease included on the list from the victim of an emergency to the involved EMS system responder.

Good relationships with your area hospitals will expedite the process for an EMS system responder to be seen and have a source patient's blood drawn. (Note that the source patient is never charged for the lab work requested by your agency and the request must be in writing. It is the agency's financial responsibility. In some jurisdictions the cost of the source patient labs becomes part of the workers' compensation case of the exposed/injured EMS system responder.)

All treatment for postexposure management should follow the recommendations. See Figures 6.6 to 6.14 for algorithms of postexposure management guidelines for hepatitis B (known

responder, anti-HBs > 10 IU/mL; unvaccinated and source unknown; known and vaccinated nonresponder; vaccine response unknown), hepatitis C, HIV, and TB and anthrax (inhalation and cutaneous) set forth by the CDC guidelines, June 2001, October 2001, September 2005, December 2005, and August 2008 or more recent updated CDC guidelines. EMS agencies can develop postexposure guidelines and flow charts such as these examples from the CDC guidelines.

## Program models

In one area of the country, five public service agencies have pooled their resources (occupational health nurses) for after-hours triage of exposure incidents. All agencies have widely disseminated an exposure control contact phone number to be used by employees in the event of an occupational exposure. The number is answered by an answering service who then pages the DICO (or on-call RN). That DICO calls the worker to determine the specifics of the exposure and then completes a standard form (see Examples 6.3 and 6.4). NFPA 1581, Standard on Fire Department Infection Control Program, 2005 edition, also has an example of a sample exposure report. If the employee needs to be seen at a hospital, the DICO calls ahead to the emergency room with basic information and request for source testing, if consent can be obtained. If the situation warrants, the hospital or infectious disease physician starts the employee on postexposure prophylaxis. Each agency follows up with their employee.

Note: A standard two-drug postexposure prophylaxis regime can cost as much as \$2000 for the required 28-day supply. In your preplanning discussions, consider asking the provider to write the first prescription for 3 to 7 days, as the regime is not always tolerated well and one of the drugs may be stopped. The individual placed on postexposure prophylaxis should be seen and evaluated at 72 hours.

Many agencies utilize Field Operations Guides (FOG) as a checklist for action in an exposure incident. See Example 6.5.

## Special situations/concerns

- In an officer-involved shooting, the officer is typically not immediately available to the DCIO/IP. Ensure someone in the command structure has on their checklist to determine if the officer experienced a blood or tissue exposure. If so, they should notify the DICO/IP so source testing can be requested of the hospital or medical examiner.
- Agencies should have a specific plan for cleaning blood and OPIM from patrol cars and transport vehicles. If inmate workers are used, they and their supervisors should be trained in exposure control methods and proper use of PPE.
- Fire departments are sometimes requested to “wash down” a scene on public property that has blood and OPIM. A safer response would be a protocol involving absorbent pads and appropriate PPE. The reason for this is to prevent the introduction of large amounts of biological material into waterways that may cause pollution concerns and increased exposure risks if blood splatters onto EMS system responders.
- Clearing homeless camps should follow a standard procedure to decrease the risk of exposure to rodents, human waste, infested bedding, needles, and booby-traps.
- There are situations in which the patient is not transported to the hospital. The patient may be pronounced dead at the scene or refuse transport. The coroner or medical examiner is responsible for ensuring the deceased source patient’s blood is drawn in a postexposure event. Many states have statutes and procedures

in place and a close cooperative working agreement with the medical examiner's office can provide the efficient completion of postexposure testing of the deceased patient. The process in some states requires a signed affidavit attesting to the circumstances of the exposure. After review by the local health authority, the source patient can be traced and requested to submit to testing. There are also provisions for court-ordered testing should a voluntary attempt be unsuccessful.

- On occasion, police, correctional facility officers, and other emergency system responders are intentionally bitten by suspects or prisoners. When such bites occur, routine medical treatment (including assessment of tetanus status) should be implemented as soon as possible, since bites can result in infection with organisms other than HIV and HBV.

## Cited References

1 Occupational transmission of *Neisseria meningitidis*-California 2009. *MMWR Recomm Rep* Nov 19 2010;59(45):1480-1483.

2 Harris S, Nicolai L. Occupational exposures in emergency medical service providers and knowledge of compliance with universal precautions. *Am J Infect Control* 2010;38:86-94.

3 Carrico R, ed. *APIC text of infection control and epidemiology*. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc., 2009; chapter 113.

4 OSHA. *Occupational exposure to blood borne pathogens precautions for emergency responders*, OSHA 3130 (Revised) 1998. Available at: [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=standards&p\\_id=10051](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051). Accessed January 24, 2013.

5 *Federal Register* Nov 2 2011;RWCA76(212).

6 *Federal Register* Nov 2 2011;RWCA76(212):67741.

7 Siegel JD, Rhinehart E, Jackson M, Chiarello L, The Healthcare Infection Control Practices Advisory Committee. *The guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007*. Available at: <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>. Accessed December 13, 2012.

8 Implementation of Section 2695 (42 USC 300ff-131) of Public Law 111-87: Infectious Diseases and Circumstances Relevant to Notification Requirements. *Federal Register* Nov 2 2011;76(212). Available at: <http://www.cdc.gov/niosh/topics/ryanwhite/pdfs/FRN11-2-2011GPO.pdf>. Accessed January 24, 2013.

9 CDC. *Bloodborne pathogens and aerosols*. Available at: <http://www.cdc.gov/oralhealth/infectioncontrol/faq/>. Accessed January 24, 2013.

## Additional Resources

Northwest AIDS Education and Training Center. Reproducible guide for postexposure prophylaxis for Occupational Bloodborne Exposures. Available at: <http://depts.washington.edu/nwaetc/resources/PEPManual.pdf>

North Dakota Ambulance Service Exposure Control Plan. Available at: <http://www.ndhealth.gov/EMS/Protocol.htm>

**Example 6.1****EXPOSURE DETERMINATION****A. Employees with Potential for Occupational Exposure to BBP**

The following categories of employees employed by the fire department are considered to have risk of occupational exposure to BBP:

1. All line personnel: All individuals in this class have a potential for occupational exposure. This includes all line firefighters, individuals that work a 40-hour week and work call-shifts, and administrative personnel that are involved in or present during ongoing fire and rescue services provided by the department.

The following job classifications are included in this category:

a.	Chief	b.	Division Chiefs
c.	Deputy Chiefs	d.	Fire Battalion Chiefs
e.	Fire Captains	f.	Fire Lieutenants
g.	Firefighters	h.	Fire Investigators
i.	Fire Inspectors	j.	EMS Specialists

Support Personnel: Other personnel who could have occupational exposure include:

a.	EMS support personnel	b.	Occupational Health Coordinator
c.	Hazardous Materials Coordinator	d.	Emergency Vehicle Technicians, delivery and shop personnel

**B. Incidents and Procedures with Potential for Occupational Exposure**

1. Firefighter/EMTs are involved in many types of incidents which have potential for occupational exposure. These incidents include, but are not limited to:

a.	Fires	b.	Extrications
c.	Forcible entries	d.	Water rescue
e.	Explosions	f.	Emergency medical calls
g.	Social problem intervention	h.	Hazmat related calls and disposition
i.	Scene clean up, decontamination, and disposal		

## EXPOSURE DETERMINATION, continued

2. Tasks performed during or following emergency response incidents which could involve exposure include but are not limited to:

	Task	Gloves	Protective eyewear	Mask	Gown
a.	Airway management/intubation/suction	Yes	Yes	Yes	No
b.	Starting IVs/IOs	Yes	No	No	No
c.	Trauma, dressing wounds	Yes	Yes	Yes	Yes
d.	Obtaining blood samples	Yes	No	No	No
e.	Public assist calls	Yes	No	No	No
f.	Moving, evaluating, or treating patients	Yes	No	No	No
g.	Administering medications	No	No	No	No
h.	Performing CPR/mouth-to-mouth resuscitation (if off-duty and no barrier device was available)	Yes	No	No	No
i.	Handling, cleaning, and disposing of contaminated equipment or materials	Yes	Yes	No	*Varies
j.	Extrication/trauma	Yes	Yes	Yes	*Varies
<p>* Depending on volume of bodily fluids present</p> <p>Source: CDC. <i>2007 guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings</i>. Available at: <a href="http://www.cdc.gov/hicpac/2007IP/2007ip_table4.html">http://www.cdc.gov/hicpac/2007IP/2007ip_table4.html</a>. Accessed January 24, 2013.</p>					

## Example 6.2

### SELECT AGENTS AND TOXINS

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at: <http://www.selectagents.gov>

#### HHS SELECT AGENTS AND TOXINS

Abrin  
 Botulinum neurotoxins  
 Botulinum neurotoxin producing species of *Clostridium*  
 Cercopithecine herpesvirus 1 (Herpes B virus)  
*Clostridium perfringens* epsilon toxin  
*Coccidioides posadasii/Coccidioides immitis*  
 Conotoxins  
*Coxiella burnetii*  
 Crimean-Congo hemorrhagic fever virus  
 Diacetoxyscirpenol  
 Eastern Equine Encephalitis virus  
 Ebola virus  
*Francisella tularensis*  
 Lassa fever virus  
 Marburg virus  
 Monkeypox virus  
 Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)  
 Ricin  
*Rickettsia prowazekii*  
*Rickettsia rickettsii*  
 Saxitoxin  
 Shiga-like ribosome inactivating proteins  
 Shigatoxin  
 South American Hemorrhagic Fever viruses  
     Flexal  
     Guanarito  
     Junin  
     Matchupo  
     Sabia  
 Staphylococcal enterotoxins  
 T-2 toxin  
 Tetradotoxin  
 Tick-borne encephalitis complex (flavi) viruses  
     Central European Tick-borne encephalitis  
     Far Eastern Tick-borne encephalitis  
     Kyasanur Forest disease  
     Omsk Hemorrhagic Fever  
     Russian Spring and Summer encephalitis  
 Variola major virus (Smallpox virus)  
 Variola minor virus (Alastrim)  
*Yersinia pestis*

#### OVERLAP SELECT AGENTS AND TOXINS

*Bacillus anthracis*  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mallei* (formerly *Pseudomonas mallei*)  
*Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)  
 Hendra virus  
 Nipah virus  
 Rift Valley fever virus  
 Venezuelan Equine Encephalitis virus

#### USDA VETERINARY SERVICES SELECT AGENTS

African horse sickness virus  
 African swine fever virus  
 Akabane virus  
 Avian influenza virus (highly pathogenic)  
 Bluetongue virus (exotic)  
 Bovine spongiform encephalopathy agent  
 Camel pox virus  
 Classical swine fever virus  
*Ehrlichia ruminantium* (Heartwater)  
 Foot-and-mouth disease virus  
 Goat pox virus  
 Japanese encephalitis virus  
 Lumpy skin disease virus  
 Malignant catarrhal fever virus  
     (Alcelaphine herpesvirus type 1)  
 Menangle virus  
*Mycoplasma capricolum* subspecies *capripneumoniae*  
     (contagious caprine pleuropneumonia)  
*Mycoplasma mycoides* subspecies *mycoides* small colony (*MmmSC*) (contagious bovine pleuropneumonia)  
 Peste des petits ruminants virus  
 Rinderpest virus  
 Sheep pox virus  
 Swine vesicular disease virus  
 Vesicular stomatitis virus (exotic): Indiana subtypes  
 VSV-IN2, VSV-IN3  
 Virulent Newcastle disease virus<sup>1</sup>

#### USDA PLANT (PPQ) SELECT AGENTS

*Peronosclerospora philippinensis*  
*Phoma glycicola* (formerly *Pyrenochaeta Yersinia pestis glycines*)  
*Ralstonia solanacearum* race 3, biovar 2  
*Rathayibacter toxicus*  
*Sclerophthora rayssiae* var. *zeae*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae*  
*Xylella fastidiosa* (citrus variegated chlorosis strain)

<sup>1</sup> A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

### Example 6.3

#### Communicable Disease Guidelines

Exposure Description	Action Required
Exposure of open skin, cuts, or breaks or mucous membranes, such as eyes, nose, or mouth to blood or body fluids. This includes needlesticks and human bites.	Clean exposed area with soap and large amounts of water; if in the mouth, rinse and spit repeatedly; flush eyes as appropriate. Provide first aid if needed. Call your DICO.

When calling the Exposure Control Line DICO, establish a procedure that is appropriate for the agency and setting. This should be addressed in the ECP.

- Identify self and your agency
- State issue briefly
- Give your call back number
- If not contacted by the DICO within 20 minutes, call the Exposure Control Line again

It is helpful if you have information about the “source person” you were in contact with and call as soon as possible, preferably from the emergency department where the patient was delivered.

- Name
- Date of birth
- Their location/contact information



**Example 6.4**

<b><i>Occupational Exposure Worksheet</i></b>		
Caller name: _____ Date: _____ Time: _____		
Employee name: _____ Exposure date: _____		
Employer: _____ Exposure time: _____		
Phone: (w) _____ (h) _____ (c) _____		
<b>Any other agencies responding to same incident?</b> _____		
<b><u>Type of Exposure:</u></b> <input type="checkbox"/> ID <input type="checkbox"/> HAZMAT	<b><u>Source of Exposure:</u></b>	
<input type="checkbox"/> Mucous membrane _____	<input type="checkbox"/> Blood _____	
<input type="checkbox"/> Needle/sharp _____	<input type="checkbox"/> Vomit _____	
<input type="checkbox"/> Open skin _____	<input type="checkbox"/> Urine _____	
<input type="checkbox"/> Intact skin _____	<input type="checkbox"/> Saliva _____	
<input type="checkbox"/> Respiratory _____	<input type="checkbox"/> Feces _____	
<input type="checkbox"/> Clothes/equip _____	<input type="checkbox"/> Respiratory _____	
<input type="checkbox"/> Airborne _____	<input type="checkbox"/> Smoke _____	
<input type="checkbox"/> Other _____	<input type="checkbox"/> Other _____	
<b><u>Narrative of exposure incident:</u></b>		
_____		
_____		
_____		
_____		
<b><u>Precautions:</u></b>		
<input type="checkbox"/> Eyewear <input type="checkbox"/> Mask <input type="checkbox"/> SCBA <input type="checkbox"/> Turnouts <input type="checkbox"/> Gloves <input type="checkbox"/> Other		
<b><u>Immunizations:</u></b>	<b><u>Counseling Issues</u></b>	
<input type="checkbox"/> HepB Vacc Date: _____	<input type="checkbox"/> HIV stats	<input type="checkbox"/> PEP
<input type="checkbox"/> Titer Date: _____	<input type="checkbox"/> Hep B	<input type="checkbox"/> Hep C
<input type="checkbox"/> Tetanus Date: _____	<input type="checkbox"/> Standard Prec	<input type="checkbox"/> Risks
<input type="checkbox"/> Tb Date: _____	<input type="checkbox"/> Blood donation	<input type="checkbox"/> Sex
<input type="checkbox"/> Other: _____	<input type="checkbox"/> Tb/Airborne	<input type="checkbox"/> Meningitis



**Example 6.5**

***Blood and Body Fluid Exposure***

**Field Operations Guide (FOG)**

Any of the following events will be considered a bloodborne exposure and require the DICO (Designated Infection Control Officer) to follow all steps outlined here.

1. Blood or amniotic fluid splash to the eyes, nose, or mouth.
2. Blood or amniotic fluid comes in contact with nonintact skin.
3. Contaminated needlestick.
4. Blood or amniotic fluid soaked clothing over nonintact skin.

The DICO will complete the following steps immediately and initial each box as completed.

- ☐ Upon dispatch contact unit and verify progress of source patient blood testing.
- ☐ Verify decontamination has been completed by the exposed employee.
- ☐ Place the unit out of service upon completion of the call.
- ☐ Contact supervisor to advise of the exposure and confirm the dispatch of the DICO.

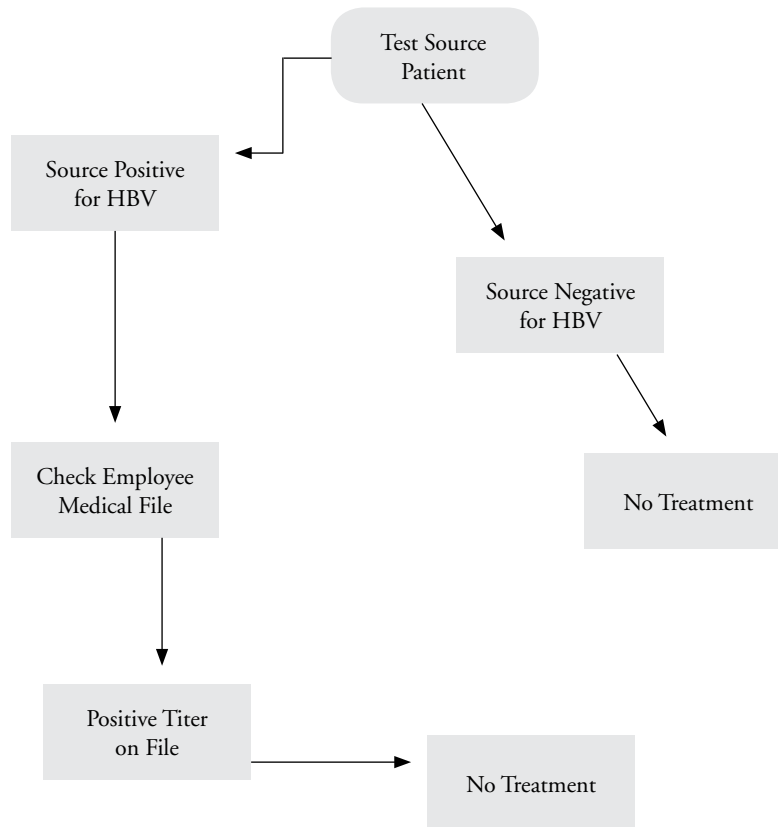
The DICO will complete the following steps as soon as possible after the exposure and initial each box as completed.

- ☐ Contact hospital for source patient testing.
- ☐ Have source blood sample drawn by authorized medical personnel.
- ☐ Verify exposed employee gets follow-up counseling and treatment, if required.

During the course of the FOG either the DICO or EMS Field Supervisor will contact the unit OIC (officer in charge) to determine destination and provide further instructions. This completed form will be presented to the DICO upon arrival.

**Figure 6.1.** Postexposure HBV Prophylaxis: Known Responder\*

(\*a responder has adequate levels of serum antibody to HBsAG [i.e., anti-HBs  $\geq$  10 mIU/mL]).

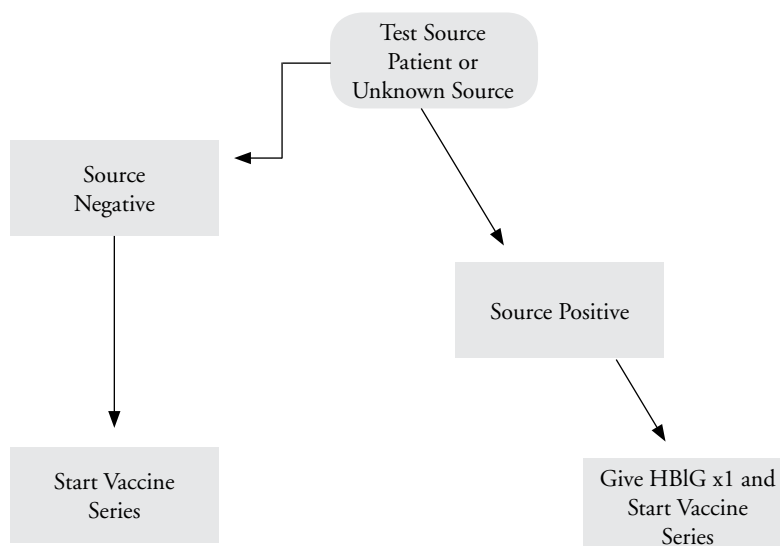


**CDC. MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008**

[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)

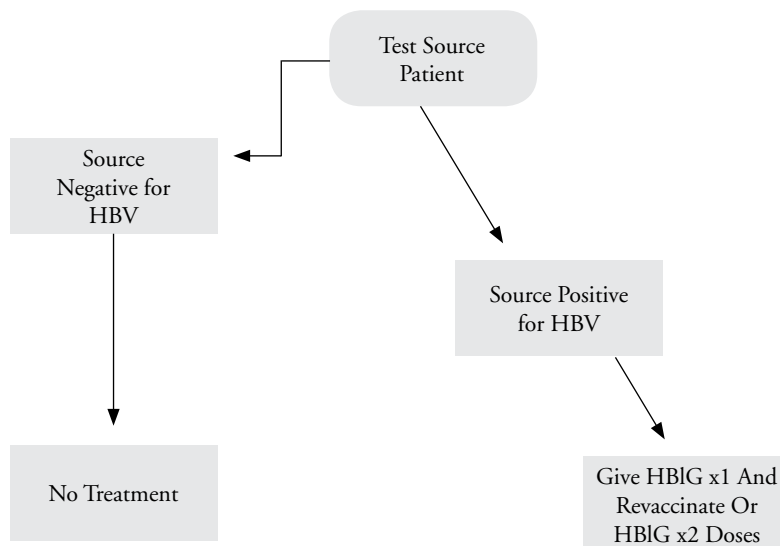
<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>

**Figure 6.2.** Postexposure HBV Prophylaxis: Nonvaccinated Employee or Source Unknown



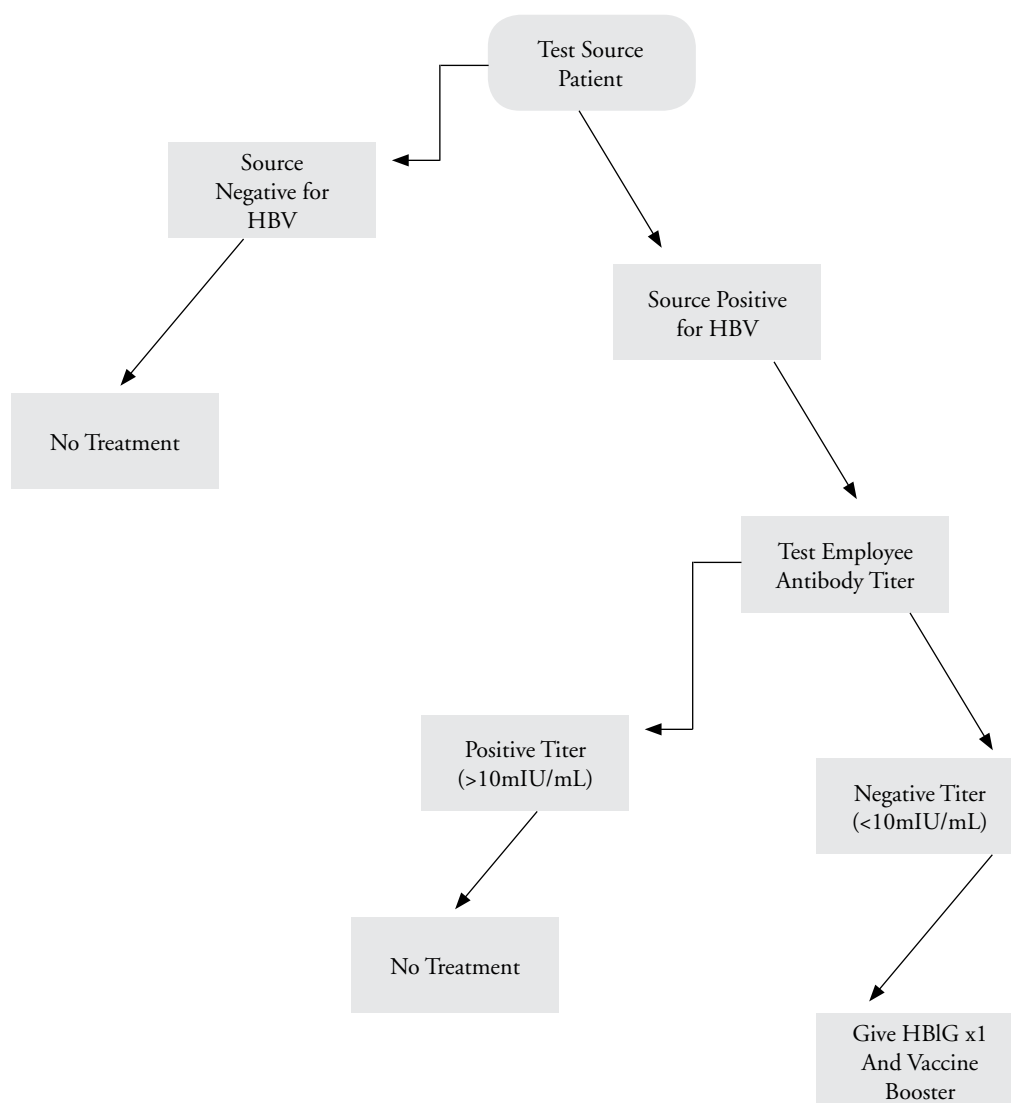
**CDC, MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008**  
[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)  
<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>

**Figure 6.3.** Postexposure HBV Prophylaxis: Known Vaccine Nonresponder



**CDC, MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008**  
[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)  
<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>

**Figure 6.4.** Postexposure HBV Prophylaxis: Vaccine Response Unknown

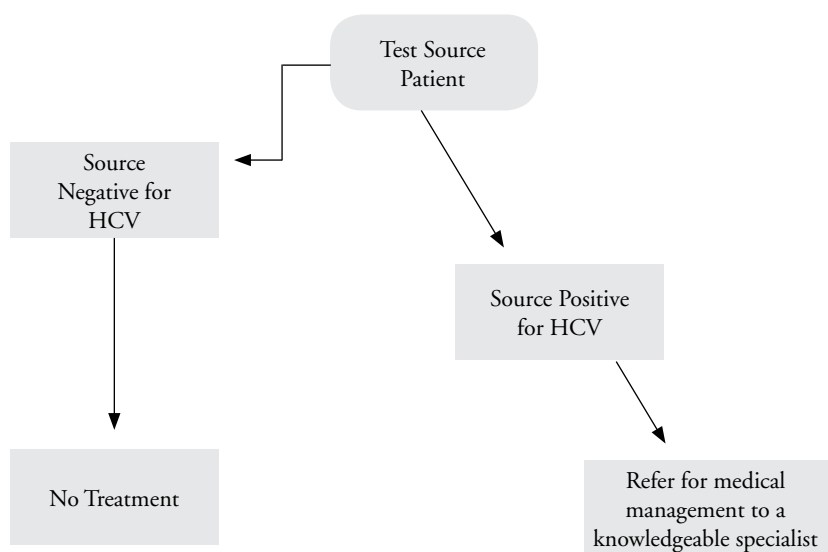


CDC, MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008

[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)

<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>

**Figure 6.5.** Post HCV Exposure Prophylaxis



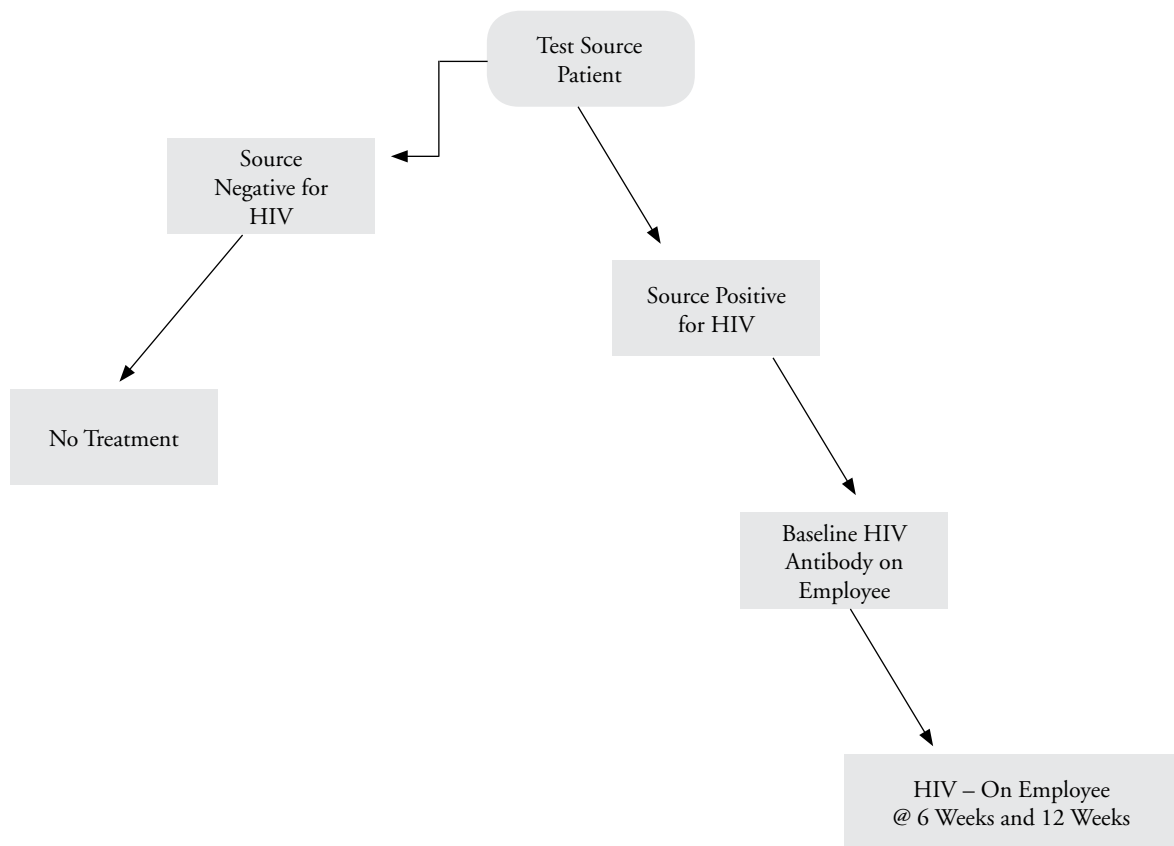
**CDC, MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008**

[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)

<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>



**Figure 6.6.** Post HIV Exposure Prophylaxis



HIV postexposure prophylaxis (PEP) should be started ASAP and preferably within hours. If this is delayed more than 24 to 36 hours, seek expert consultation. PEP should continue for 28 days. Consult an expert for the recommended HIV PEP drug regimen. If information on the source patient is unknown, and the decision to start PEP is made (based on risk factors, exposure type, etc.), PEP should not be delayed; changes can be made as needed after PEP is started. The exposed EMS system responder should be reevaluated within 72 hours as additional information about the source patient is obtained. If source patient is found to be HIV-negative, PEP should be discontinued.

#### PEP Resources

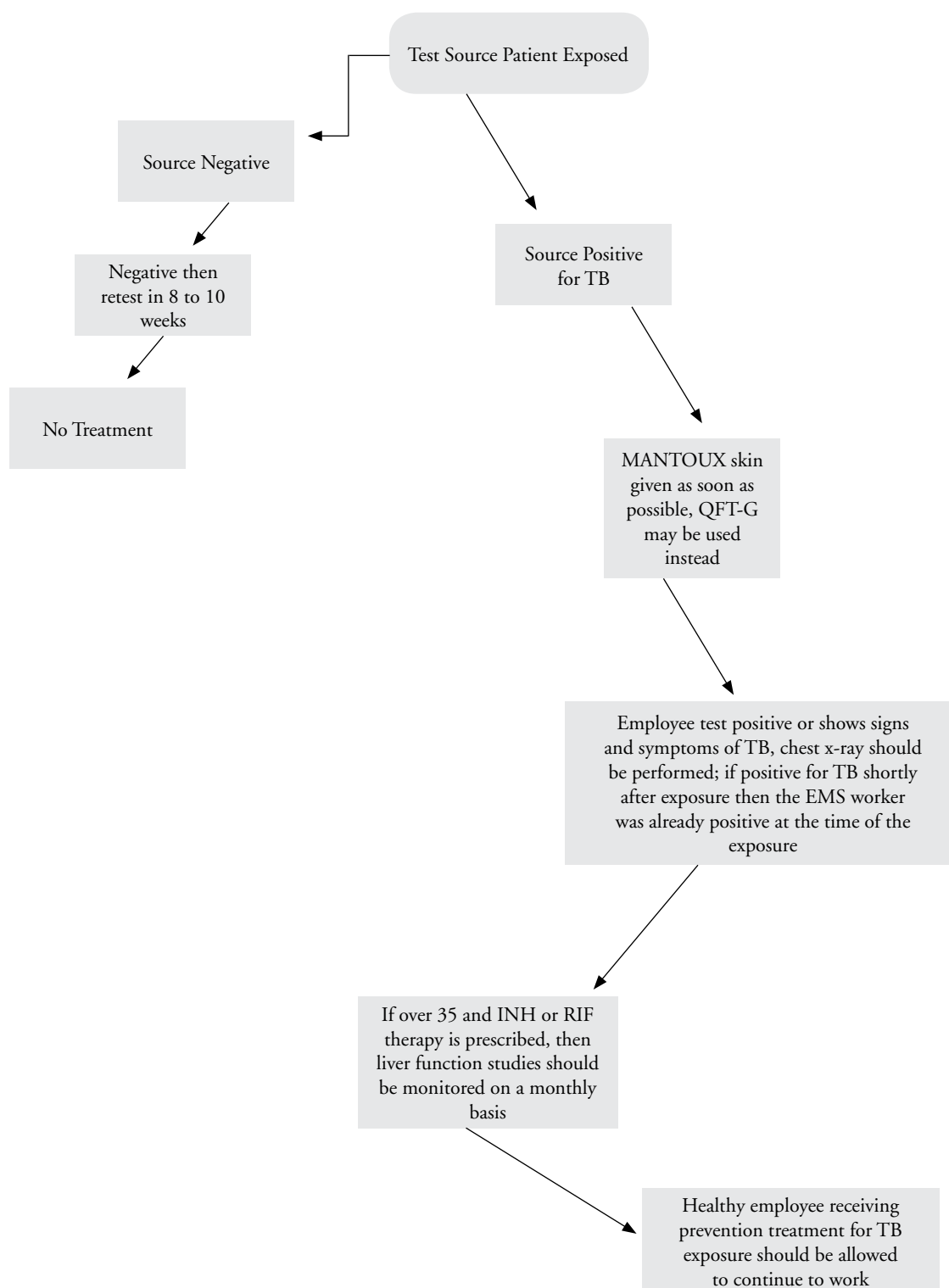
National Clinicians' Post-exposure Prophylaxis Hotline (PEpline) 1-888-448-4911

**CDC, MMWR, June 29, 2001, Sept. 30, 2005, August 1, 2008**

[http://www.mpaetc.org/downloads/PEP%20final%20\(2006\).pdf](http://www.mpaetc.org/downloads/PEP%20final%20(2006).pdf)

<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm>

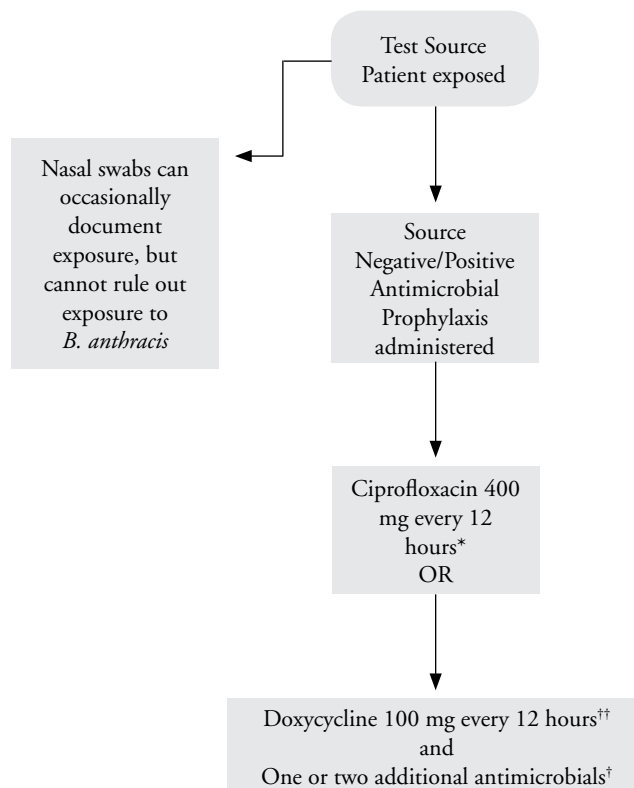
**Figure 6.7.** Post Tuberculosis Exposure Prophylaxis



CDC, MMWR, December 16, 2005

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm>

**Figure 6.8.** Post Anthrax (Inhalation) Exposure Prophylaxis



**CDC, MMWR, October 26, 2001**

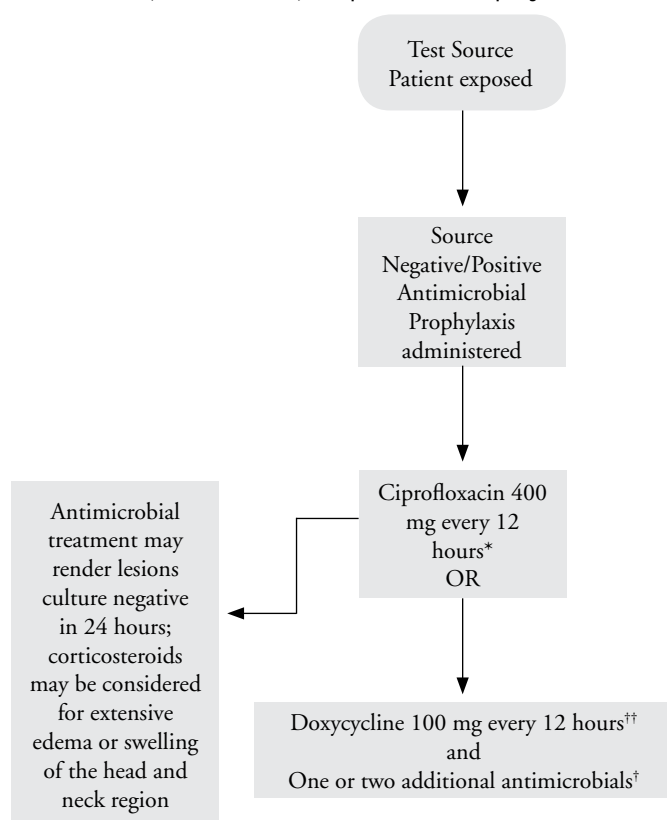
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5042a1.htm>

\* For gastrointestinal and oropharyngeal anthrax, use regimens recommended for inhalation anthrax.

† Other agents with *in vitro* activity include rifampin, vancomycin, penicillin, ampicillin, chloramphenicol, imipenem, clindamycin, and clarithromycin. Because of concerns of constitutive and inducible beta-lactamases in *Bacillus anthracis*, penicillin should not be used alone. Consultation with an infectious disease specialist is needed.

†† If meningitis is suspected, doxycycline may be less optimal because of poor central nervous system penetration.

**Figure 6.9.** Post Anthrax (Cutaneous) Exposure Prophylaxis



**CDC, MMWR, October 26, 2001**

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5042a1.htm>

\* Cutaneous anthrax with signs of systemic involvement, extensive edema, or lesions on the head or neck require intravenous therapy, and a multidrug approach is recommended.

† Other agents with *in vitro* activity include rifampin, vancomycin, penicillin, ampicillin, chloramphenicol, imipenem, clindamycin, and clarithromycin. Because of concerns of constitutive and inducible beta-lactamases in *Bacillus anthracis*, penicillin should not be used alone. Consultation with an infectious disease specialist is needed.

†† If meningitis is suspected, doxycycline may be less optimal because of poor central nervous system penetration.

## Section 7: Bioterrorism and Infectious Disease Emergency Preparedness

### Bioterrorism

Bioterrorism refers to the use of biological agents on civilian or military populations, animals, or crops. A combination of factors have raised concerns about the actual use of bioterrorism agents, including the breakup of the former Soviet Union and the concomitant dispersal of scientists and agents involved in bioterrorism research, the rise of radical groups focused on destroying what they believe to be evil forces, and the discovery of Iraq's stockpiled anthrax, botulinum toxin, and other biological warfare agents. There are a broad range of potential bioterrorism agents, including bacteria, viruses, and other toxins of microbial, plant, or animal origin.

### Nature of the bioterrorism threat

The most likely route of dissemination is an aerosolized release of 1 to 5  $\mu\text{m}$  particles. Other methods of dissemination include oral (intentional contamination of food/water supply), percutaneous, infected animal vector (e.g., release of infected fleas), and human-to-human spread (individual infected with communicable disease walking among a crowd of healthy people). Other possible distribution methods, such as mailing a letter or package containing infectious particles, may also be feasible.

### Pandemics

A pandemic is a large-scale outbreak that affects at least two continents. Unlike a bioterrorism attack or outbreak of an emerging infection, a pandemic is usually not an event that occurs suddenly, although a pandemic can strike without warning,

as evidenced by the 2009 H1N1 pandemic. The World Health Organization (WHO) describes six phases of a pandemic, starting with the period in which there are few to no human cases from the organism/disease to the period in which there is efficient and sustained disease spread from person to person. The six WHO pandemic phases are outlined in Table 7.1. Pandemics are expected to hit communities in multiple waves, each lasting approximately 6 to 8 weeks, making response a more prolonged event than with other types of disasters. Each pandemic wave will cause significant patient surge, including an increased need for emergency medical services. During an influenza pandemic, attack rates will likely be between 15 and 35 percent across all populations; young children and the elderly are expected to be disproportionately affected and have attack rates close to 40 percent.

**Table 7.1.** The six phases of pandemic

Phase	Description of the phase
1	Low risk of human cases
2	Higher risk of human cases
3	No or very limited human-to-human transmission
4	Evidence of increased human-to-human transmission
5	Evidence of significant human-to-human transmission
6	Efficient and sustained human-to-human transmission

Adapted from World Health Organization. *Current WHO phase of pandemic alert 2008*. Available at: [http://www.who.int/topics/avian\\_influenza/en/](http://www.who.int/topics/avian_influenza/en/)

There are a number of agents that could cause a pandemic, including SARS and plague. Historically, influenza has caused the most pandemics and is expected to cause others in the future. One of the most recent pandemic threats has been H5N1, a strain of influenza A also called “avian influenza.”

## **Nature of the pandemic threat**

As of December 2012, WHO indicates that we are in pandemic phase 3: there is an agent with the capacity to cause a pandemic (influenza A/H5N1), but there is currently no or very limited human-to-human transmission. There have been 610 human cases and 360 deaths from H5N1 avian influenza as of December 2012. It is not known whether H5N1 will continue to mutate and adapt to become more easily spread from person to person, resulting in a pandemic. It is also possible that another strain or organism could emerge and cause a pandemic. A future influenza pandemic is considered inevitable, but it is not known what strain will be involved or when the event will occur.

## **Infection prevention procedures**

The amount of DICO involvement in disaster response depends on the agent involved. In an infectious disease disaster, involvement will be critical, especially if the agent is communicable. Many agents of bioterrorism are not transmitted from person to person, but some are. Most emerging infectious diseases are communicable, but a few are not.

Bioterrorism agents and emerging infectious diseases that are communicable pose the greatest risk to society. Examples of potential infectious disease disasters that involve communicable diseases include pneumonic plague, smallpox, viral hemorrhagic fever viruses, SARS, and pandemic influenza. In these instances, infection prevention will be essential to control the outbreak, prevent future cases, and decrease morbidity and mortality associated with the event.

## **Isolation, personal protective equipment, and hand hygiene**

In addition to pharmacological interventions (anti-infective therapy, chemoprophylaxis, and vaccination), nonpharmacological interventions should be implemented to prevent and control disease spread during an infectious disease disaster. The primary nonpharmacological interventions involve isolation, PPE, and hand hygiene use as discussed previously in this guide. In regard to bioterrorism, the exact necessary infection prevention procedures cannot be estimated before an attack occurs. It depends on many factors, including how soon the release is detected (i.e., whether decontamination and prophylaxis are necessary), how soon the diagnosis is made, how soon appropriate isolation was initiated (i.e., the number of affected individuals), and what agent was used (i.e., whether the agent is contagious). Hand hygiene will be essential during any infectious disease disaster, and will aid in disease spread as well as protecting EMS personnel from exposure and illness.

Any time a bioterrorism-related or emerging infectious disease is suspected, infection prevention guidelines for that specific agent/disease should be followed. At the beginning of an infectious disease disaster when the agent may not have been identified or when there is not enough evidence to determine the disease transmission route, EMS system responders and DICOs need to base infection prevention decisions for patient care on syndromes and symptomology. This is referred to as syndrome-based isolation/control measures. These measures are especially important during an infectious disease disaster involving a newly emerging infection because there may be limited or no information available on the causative agent. Table 7.2 outlines the isolation categories and control measures to be used based on syndromes and symptomology.

SARS was an example of this situation. When SARS first emerged in 2003, the causative agent was unknown, as was the transmission route and control measures needed to prevent disease spread. Infection prevention decisions were made on

**Table 7.2.** Isolation categories and control measures to be used based on syndromes and symptomology

Symptoms/syndrome	Isolation precaution category <sup>a,b</sup>
<b>Respiratory</b> Cough, runny nose, watery eyes Fever (>101.1°F) and cough in adults <sup>c</sup> Fever (>101.1°F) and cough in children <sup>3</sup>  Fever (>101.1°F), cough with bloody sputum, and weight loss or with upper lobe pulmonary infiltrate in an HIV–negative patient or any lobe of an HIV+ patient <sup>3</sup> Fever (>101.1°F), cough, and pulmonary infiltrate in any lobe in patient with a travel history to country with active cases of SARS or avian influenza within past 10 to 21 days <sup>c</sup>	Droplet Droplet Droplet Contact Airborne and Contact, plus eye protection when performing aerosol-generating procedure  Airborne and Contact, plus eye protection
<b>Diarrhea and vomiting</b> Vomiting Acute diarrhea with likely infectious cause in an incontinent or diapered patient Watery or explosive stools, with or without blood	Standard Contact  Contact
<b>Skin</b> Fever (>101.1°F) and rash Fever (>101.1°F), upper chest rash, and stiff/sore neck Eye infections (drainage from eye) Draining wound/lesion that cannot be covered	Airborne Droplet Standard Contact
<b>Rash</b> Itchy rash without fever Petechial/ecchymotic with fever Rash and positive history of travel to an area with a current outbreak of VHF in the 10 days before fever onset  Maculopapular with cough, coryza, and fever Vesicular, especially if centrifugal in pattern	Contact Droplet for 24 hours of antimicrobial therapy Droplet and Contact, plus eye protection (goggles or face shield). Add N95 or equivalent when performing aerosol-generating procedures. Airborne Airborne and Contact

<sup>a</sup>Always use Standard Precautions.

<sup>b</sup>If the causative agent is known, the appropriate isolation precautions for that disease should be used.

<sup>c</sup>A temperature of 100°F should be used as the identifier for potential infection to identify the elderly or immunocompromised individuals whose physiological changes tend to mask normal signs of infection. In addition, clinical judgment should always be used.

Adapted from Rebmman T, Wilson R, Alexander S, et al. *Infection prevention and control for shelters during disasters*. Washington, DC: Association for Professionals in Infection Control and Epidemiology; 2008. Available at: <http://www.apic.org> and Siegal JD, Rhinehart E, Jackson M, et al., and the Healthcare Infection Control Practices Advisory Committee. *Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007*. Available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

the basis of patients' symptoms, epidemiological information as it became available, and basic infection prevention principles.

During an infectious disease disaster in which hospitals will be full and potentially contagious patients may be triaged to alternate care sites,

emergency responder agencies should consider educating the public regarding how to implement basic infection prevention strategies in nonhospital settings. This may include isolation and PPE use in long-term care, alternate care sites, home health, medical clinics, community-based evacuation shelters, and any other care sites



that administers healthcare services or houses potentially contagious patients.

## **Healthcare personnel surge capacity**

EMS agencies, organizations, and businesses, including healthcare, should expect high absenteeism rates during an infectious disease disaster.

Absenteeism is expected to be higher during an infectious disease disaster than other types of mass casualty events. Up to 20 percent of the workforce may be affected by illness at the same time during a pandemic, and others will be unable or unwilling to work due to family obligations or fear. WHO recommends that emergency managers plan for a 40 percent absenteeism rate during the peak of pandemic. Healthcare personnel are expected to be infected at the same rate as the general population during an infectious disease disaster, which will further reduce EMS agencies' ability to respond to such an event. EMS agencies need to plan for this increase in healthcare personnel absenteeism. Some recommended ways for increasing healthcare worker surge capacity include the following:

- Having back-up contracts for obtaining extra staff
- Providing incentives to acquire and retain staff
- Prioritizing EMS personnel for anti-infective therapy, prophylaxis, and vaccination
- Offering anti-infective therapy, prophylaxis, and vaccination to family members of EMS personnel

## **Protection of emergency medical services personnel**

EMS personnel will be at high risk of exposure during an infectious disease disaster. Policies and procedures must be in place to protect EMS from exposure and minimize the risk of infection.

One option is to provide pre-event vaccination to EMS professionals. Beginning in 2009, the

CDC recommended that emergency response agencies consider offering staff the anthrax vaccine series pre-event as a way of protecting workers of exposure following an anthrax bioterrorism attack. Other pre-event vaccinations, such as seasonal influenza, should also be offered to EMS professionals to provide protection during an infectious disease disaster. Post event, all EMS professionals should be offered event-specific vaccine when applicable; an example was the prioritization of EMS to receive the H1N1 influenza vaccine during the early part of the H1N1 pandemic when vaccine supplies were insufficient. EMS should be prioritized to receive anti-infective therapy, prophylaxis, and vaccination during an infectious disease disaster when supplies are limited. EMS agencies should partner with community disaster planners to ensure that EMS professionals are included in the list of prioritized groups for pharmaceutical interventions.

EMS personnel should be educated regarding appropriate PPE to use during an infectious disease disaster and ensure that adequate PPE supplies are available. This includes choosing the appropriate PPE to wear for patient care activities as well as when handling suspicious letters or packages that may contain infectious particles. EMS personnel should be educated regarding how to handle suspicious letters or packages to reduce their risk of exposure while maintaining chain of custody for the purposes of investigating potential bioterrorism incidents.

PPE and other medical supplies are expected to be insufficient or depleted during an infectious disease disaster. Many hospitals are developing prioritization plans for allocation of PPE when supplies are limited. EMS agencies need to develop similar plans. PPE allocation should be made based upon the known or suspected risk of exposure during patient care procedures, and on the risk of disease for each worker. For example, aerosolizing procedures, such as cardiopulmonary resuscitation and providing nebulizer treatments, pose a high risk of exposure during outbreaks involving an

airborne or droplet spread disease. During events when PPE is limited, EMS agencies should consider prioritizing staff performing aerosolizing procedures to receive N95 respirators or other respiratory protection. EMS personnel who are at high risk of complications of infection, such as pregnant or immunocompromised workers, should either be prioritized to receive PPE or avoid performing high-risk procedures when PPE supplies are limited. Whenever possible, EMS agencies should develop a pre-event memorandum of agreement (MOA) or memorandum of understanding (MOU) with vendor(s) to ensure access to PPE and other medical supplies during a disaster. MOAs and MOUs will be most critical in preparing for biological disasters.

## **Decontamination**

Decontamination may or may not be an issue after an infectious disease disaster, depending on the following factors:

1. Type of event (bioterrorism versus emerging infectious disease outbreak or pandemic)
2. Causative agent
3. How soon the event is identified
4. Source of concern (environment or patient).

Most infectious disease disasters, including bioterrorism attacks, will likely not require patient decontamination. Pandemics and outbreaks of emerging infectious diseases will not require patient decontamination. In the event of a covert release of a biological agent, patients will not become symptomatic and present to healthcare institutions until days to weeks after the exposure. In this instance, they will most likely have bathed and changed their clothes, thus decontaminating themselves. Only in the event of an announced bioterrorism attack (within 12 to 14 hours after the release) will exposed individuals need to be decontaminated. Patient decontamination consists of bathing, including shampooing of hair, with plain soap and water and changing their

clothing. EMS personnel are likely to be needed in performing patient decontamination in a community. It is essential that EMS professionals are educated about proper patient decontamination procedures to minimize exposure risk to patients and themselves. EMS personnel should participate in periodic exercises involving patient decontamination to ensure they are knowledgeable about these procedures and can perform them appropriately.

Given existing knowledge, environmental decontamination is not considered necessary for outside sources, such as streets, cars, or the outside of buildings after a bioterrorism attack. This is because weather plays a key role in rapidly disseminating biological agents in outside air.

Indoor environmental sources may require decontamination strategies after an infectious disease disaster, but the interventions vary according to the agent involved and the nature of the event. For example, more stringent decontamination methods are necessary for a bioterrorism attack using anthrax because of the hardy nature of spores. As the 2001 bioterrorism attacks illustrated, equipment or areas may require specialized decontamination strategies, such as contained buildings, ventilation systems, or machinery with small parts. EMS personnel may be the first responders on the scene of a potential bioterrorism attack and should be trained on the proper procedures for performing environmental decontamination, including choosing appropriate disinfectants and PPE to wear to protect themselves from exposure during decontamination procedures.

Other agents—especially those that are spread via fomites/contaminated surfaces—require diligent environmental decontamination as well. Strict adherence to environmental decontamination should help reduce disease spread in these situations. For EMS agencies, this includes frequent cleaning/disinfection of the EMS vehicle and medical equipment. Areas within the vehicle that are touched most often, such as stretcher

rails, cabinet handles, etc., should be cleaned/disinfected frequently to minimize bioburden in the environment. Disinfectants used for environmental decontamination should include EPA-registered germicides. All reusable patient care equipment should be disinfected between patients.

## Exercises and drills

As part of infectious disease disaster preparedness, it is essential that EMS agencies participate in exercises and drills to test their emergency management plan. EMS exercises and drills should periodically include a biological agent scenario in order to assess the agency's ability to respond to an infectious disease disaster. Whenever possible,

these exercises need to be community-wide—involving EMS agencies, healthcare facilities/agencies (including long-term care and home health), and community response agencies—to obtain a true sense of the community's preparedness for this type of event.

## Cited References

1. Carrico R, ed. *APIC text of infection control and epidemiology*. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc., 2009; chapters 117 and 118.
2. CDC. *Strategic national stockpile (SNS)*. Available at: <http://www.cdc.gov/phpr/stockpile/stockpile.htm>. Accessed January 25, 2013.

## Section 8: Education, Training, Compliance Monitoring, and Summary

### Key concepts

- Education is a critical component of every infection prevention program and must be supported accordingly.
- Training must be presented by a qualified instructor at an educational level and in a language that EMS system responders understand, and workers must have the opportunity to ask the trainer questions.
- Standard/planned training and just-in-time training are both useful methods of training EMS system responders on infection prevention.
- EMS system responders are more likely to comply with infection prevention strategies if they understand the rationale for the prevention strategies.
- Successful programs stress the importance of preventing transmission of diseases to EMS system responders, coworkers, their families, and patients.
- EMS system responders must have the opportunity to ask questions and be able to use the DICO as a resource throughout their career.
- EMS system responders are constantly bombarded with new information and therefore infection prevention must be presented often and be reinforced.
- Infection prevention education should be updated regularly and have evidence-based best practices, regulatory requirements, and compliance as its foundation. Eliminate fear-based training.
- The value of a vaccination program and postexposure medical follow-up (counseling and education) cannot be understated.

Emergency Medical Services are delivered in various ways to communities. Ambulance companies, EMS departments, fire departments, law enforcement agencies, and volunteer organizations must continue to provide quality patient care. Accordingly, agencies must ensure all EMS system responders have the knowledge and skills to safely respond to medical emergencies. EMS system responders need reinforcement of their knowledge of standard infection prevention precautions and ways to prevent occupational exposures.

DICOs have to ensure that EMS system responders undergo continuing education, specialty training, and just-in-time training to keep up to date on a wide variety of information. Educational programs need to be concise and to the point. A quick drill information session at roll call in the morning before crews “hit the street” is one example of how a program could be reinforced and updated. See Example 8.1 for an example of a quick drill on MRSA.

**Example 8.1.** Sample quick drill for preventing MRSA infections

**Quick Drill**  
**HOT TOPIC: MRSA**



**There has been a sharp increase in documented exposures to MRSA. Some firefighters' cases of MRSA have been so severe they required hospitalization.**

**Here are some quick facts regarding MRSA:**

- Staph is commonly found on the skin or in the nares (nasal passages) of normally healthy individuals. A small number of these people get MRSA.
- Most of these skin infections are minor (e.g., pimples and boils) and can be treated without antibiotics (also known as antimicrobial or antibacterial).
- Staph bacteria also can cause serious infections (e.g., surgical wound infections, bloodstream infections, and pneumonia).
- Transmission occurs when EMS system responders contact purulent sites of infection or common items found on apparatus or in stations such as stethoscopes or other medical equipment, the remote control, kitchen counter, telephone, and door handles.
- **HANDS** of personnel are the most common mode of transmission.

**Here are some things you can do to avoid MRSA:**

- Cover patient's draining wounds with clean bandages and use Contact Precautions.
- Wash hands (at least 30 seconds with liquid soap and water), especially after contact with a contaminated wound.
- Launder clothing after contact with a contaminated area on the skin. Dry clothes at least 30 minutes on high.
- Avoid sharing items (e.g., towels, bedding, clothing, razors, or athletic equipment) that may become contaminated by contact with wounds or skin flora.
- Disinfect/clean medical and sports equipment, kitchen counters, and other surfaces with an approved disinfectant or diluted bleach.
- Do not bring contaminated items into station. Decontaminate kits and other items before you go in!!

## Training

Training issues have been presented throughout this guide. OSHA standards require new employee infection prevention training to include the agency's Exposure Control Plan, and EMS system responders have to undergo this training before they go on medical calls. The importance of annual infection prevention training cannot be overstated. Training needs to be documented with the date (within a year of the previous date of training), content of training, trainer's name with credentials, and names and job titles of students attending. EMS system responders should have access to infection prevention information at all times whether it is in hard copy form in their rig, at a station, or posted on the agency's intranet site.

## Compliance monitoring

Compliance monitoring verifies that the programs you implement to keep EMS system responders safe are working. It also ensures your agency is in compliance with OSHA and/or other federal regulatory standards. Compliance monitoring also drives your training program as it identifies any training needs or problems. Agencies need to establish time frames for monitoring and disciplinary action if policies are not followed. Samples of compliance monitoring forms are provided at the end of this section.

EMS agencies can adopt the HHS seven fundamental elements for developing an effective compliance program<sup>1</sup>:

1. Implement written policies, procedures, and standards of conduct
2. Designate a compliance officer and compliance committee
3. Conduct effective training and education
4. Develop effective lines of communication
5. Enforce standards through well-publicized disciplinary guidelines
6. Conduct internal monitoring and auditing
7. Respond promptly to detected offenses and develop corrective action

Also see OSHA's Enforcement Procedures for the Occupational Exposure Bloodborne Pathogens, which can be found at: [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=DIRECTIVES&p\\_id=2570](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570)

## Regulations

Federal and state regulations, including OSHA's Bloodborne Pathogens standard, Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030, require that all healthcare workers, including EMS system responders, be provided with information and training on bloodborne pathogen exposure. Employers must ensure that their workers receive regular training that covers all elements of the standard. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Training records must be kept for 3 years. Agencies must be aware that the standard does not specifically address all of the communicable diseases/pathogens and risks EMS system responders face. Therefore, it is extremely important the person in charge of each agency's infection prevention program—whether it be the EMS medical director, managers, fire chief, occupational health nurses, DICO, etc.—keep up to date with current guidelines, standards, initiatives, program resources, and emerging diseases. A quality infectious disease prevention education program for EMS system responders is imperative.

## Components infection prevention education

Education related to infection prevention is an ongoing, constantly changing curriculum. Education for personnel should include the following components:

- Explanation of the agency's written Exposure Control Plan and location of plan for employee access

- Agency's administrative policies and procedures to ensure employee safety
- Explanation of the OSHA and/or local standards, including contents and compliance
- Infection prevention procedures and use of PPE such as gloves, goggles, and masks
- Recognition of tasks that may result in exposure to blood and OPIM
- Mandatory use of and compliance with appropriate safety devices and methods
- Evaluation, reporting, treatment, and postexposure management of significant exposures to blood and/or body fluids
- Documented symptoms of illnesses, epidemiology, portals of exposure
- Disposal of infectious and/or contaminated waste and sharps disposal
- Current infectious, emerging disease, and bioterrorism education
- Immunization updates and policies
- Education and techniques to minimize risks in the field
- Long-term consequences and dangers of noncompliance with Standard Precautions
- Work restriction guidelines (see Table 2.2)
- Documentation of agency's incidents (annual numbers) and types of employee exposures for each incident
- Reinforcement of potential exposure risks, even from seemingly "healthy" patients
- Understanding risks and causes of disease migration to regions of no previous disease incidence from an increasingly mobile population

Successful infection prevention education for EMS system responders must stress the importance of preventing transmission of diseases while adhering to local and federal standards. Documentation of the training should include a posteducation evaluation to assure all impacted personnel understand the importance of infection prevention and their safety and health risks.

There are many resources available to EMS agencies to create a quality infection prevention education program, including this guide. Contact your local, county, or state health department for further assistance. Other possible sources of assistance include area EMS, Fire, Public Safety, or Law Enforcement agencies. Many have programs in place and will share them at no cost. DICOs and program administrators must stay current on infectious diseases and infection prevention issues, laws, and regulations applicable to their departments. Practices must be evidence-based.

It is imperative that leadership supports and emphasizes the importance EMS system responder protection and patient safety. Patient care, devices, types of patients, and procedures change rapidly and EMS system responders have to be properly educated to avoid injury and exposure. The cost of training pales in comparison to the cost of treating one exposure or sharps injury. A properly implemented infection prevention program can save an agency countless dollars from OSHA fines and the fees associated with unnecessary emergency department visits. It can also prevent human and organizational resource issues related to an employee exposure such as emotional trauma, replacement costs, increased insurance rates, fear of exposing other EMS system responders, and unwanted media attention. Strong leadership is the driving force behind a quality infection prevention program.

## Guide to Infection Prevention in Emergency Medical Services

<b>Compliance Checklist* – General Infection Prevention</b>			
Practice Performed			Date: _____
Policies/Task/Procedure	Yes	No	Comments
1. Written infection prevention policies and procedures are available and current	<input type="checkbox"/>	<input type="checkbox"/>	
2. Personal protective equipment was available, donned, and removed appropriately	<input type="checkbox"/>	<input type="checkbox"/>	
3. Hand hygiene supplies provided and appropriate hand hygiene observed	<input type="checkbox"/>	<input type="checkbox"/>	
4. Gloves were used according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
5. Gloves were appropriately discarded after patient care	<input type="checkbox"/>	<input type="checkbox"/>	
6. Protective eyewear (goggles) were used according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
7. Masks were used according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
8. PPE was properly disposed of according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
9. All sharps were disposed of in a puncture-resistant container	<input type="checkbox"/>	<input type="checkbox"/>	
10. Filled sharps containers are disposed of according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
11. Vehicles were cleaned following medical calls	<input type="checkbox"/>	<input type="checkbox"/>	
12. Cleaning/decontamination was done using disinfectant/bleach according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
13. Station environmental services were cleaned/disinfected according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
14. Decon station is appropriately marked and used according to policy	<input type="checkbox"/>	<input type="checkbox"/>	
15. Infection prevention policies and procedures are reassessed at least annually or according to state or federal requirements	<input type="checkbox"/>	<input type="checkbox"/>	

**Employee Signature:** \_\_\_\_\_

**Infection Prevention Staff/DICO** \_\_\_\_\_

**Comments:**

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\*Adapted from CDC. Infection prevention checklist for outpatient settings; minimum expectation for safe care. Available at: <http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf>. Accessed January 25, 2013.



## Guide to Infection Prevention in Emergency Medical Services

Infection Control Policy and Checklist*			
Review the recommendations for disinfection procedures below. Utilize this checklist to ensure daily and periodic cleaning and disinfection control is practiced at your station.			
General	Yes	No	
All hard environmental surfaces are cleaned and disinfected daily with an EPA-registered product	<input type="checkbox"/>	<input type="checkbox"/>	
Light switches, doorknobs, door push bars, elevator controls, handrails, and community phones are disinfected daily with an EPA-registered product	<input type="checkbox"/>	<input type="checkbox"/>	
All hard flooring is cleaned and disinfected daily with an EPA-registered product	<input type="checkbox"/>	<input type="checkbox"/>	
Mop heads and buckets utilized for restrooms, locker rooms, and showers should be independent from program areas and office space; mop heads are cleaned and disinfected weekly	<input type="checkbox"/>	<input type="checkbox"/>	
Restrooms: wall dispensers are utilized for liquid soap (no bar soap)	<input type="checkbox"/>	<input type="checkbox"/>	
Exercise/Weight Rooms			
Grip areas on weight bars, dumbbells, and machines are wiped down at the beginning of day (shift), between each use, end of day (shift) with an EPA-registered product or 1:100 bleach solution; grip areas should not be taped	<input type="checkbox"/>	<input type="checkbox"/>	
Wall padding, lifting benches, stationary bike seats, and/or floor mats are cleaned daily with an approved product or 1:100 bleach solution	<input type="checkbox"/>	<input type="checkbox"/>	
Wall dispensers for hand cleaner ( $\geq 70\%$ alcohol) are placed at each entry/exit door; signage to indicate minimum use: upon entering/leaving facility	<input type="checkbox"/>	<input type="checkbox"/>	
Shower Rooms/Locker Rooms			
Showers and locker rooms (shower area, locker room floors, and benches) are cleaned and disinfected daily with an EPA-registered product and wall dispensers are utilized for liquid soap and are placed within or directly adjacent to showers (no bar soap)	<input type="checkbox"/>	<input type="checkbox"/>	
Used towels or linens utilized are only handled by employees with gloves	<input type="checkbox"/>	<input type="checkbox"/>	
Towels or linens laundered in EMS facilities are washed at 160°F and dried in a clothes dryer	<input type="checkbox"/>	<input type="checkbox"/>	
Sports Equipment			
All sports equipment used during the day is cleaned and disinfected daily with an EPA-registered product	<input type="checkbox"/>	<input type="checkbox"/>	

\*Permission to use this checklist, from Ed Neid, Deputy Chief, Tucson Fire Dept.

1 U.S. Department of Health and Human Services, Office of the Inspector General. Publication of OIG compliance program guidance for clinical laboratories. *Federal Register* 1998;63(163).

## **References and Resources**

CDC. General Resources on Bloodborne Pathogens, Engineering Controls and Personal Protective Equipment. Available at: <http://www.cdc.gov/niosh/topics/bbp/universal.html> Accessed December 13, 2012.

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International Association of Firefighters, IAFF, Occupational Disease. <http://www.iaff.org/hs/index.htm> Accessed December 13, 2012.

The Northwest AIDS Education and Training Center. Postexposure Prophylaxis for Occupational Bloodborne Exposures. Available at: <http://depts.washington.edu/nwaetc/resources/PEPManual.pdf>. Accessed December 13, 2012.

# APPENDIX A: Sample Ambulance Cleaning Procedures

## Salt River Fire Department

### ***Ambulance Cleaning Procedures***

*Used with permission courtesy of Salt River Fire Department, Scottsdale, Arizona.*

### **Purpose**

To ensure that ambulances that are being used for patient transport are properly cleaned after every transport in a standardized manner. To provide for the most sterile environment for Fire Department personnel and the patients they serve. This cleaning and disinfecting procedure is required and essential to ensure employee safety as well as that of the patients that are treated and transported daily.

### **I. Cleaning the vehicle and EMS equipment between calls and at the end of the shift.**

(This should be monitored by the station Captain, whenever possible.)

- A. Personal Protective Equipment (PPE) is used:
  - 1. Isolation gown (if necessary)
  - 2. Mask (if necessary)
  - 3. Eye protection (MANDATORY)
  - 4. Booties (if necessary)
  - 5. Gloves (MANDATORY)
- B. Cleaning and disinfecting of equipment should be performed at the receiving medical facility as much as possible. Some facilities are equipped with a designated area to remove heavily contaminated equipment. Large items can be taken to this area and the majority of the contaminates hosed off into a containment area. Complete PPE should be worn in this area. The fewer contaminated items on board, the lesser the risk to exposure. Some equipment items may take extensive cleaning and decontamination efforts. These items must be red-bagged and transported back to quarters for immediate cleaning.
- C. To clean, deodorize, and disinfect hold the cleaning agent mixture dispenser 10 inches from the surface and atomize with quick short strokes, spraying evenly on contaminated or potentially contaminated areas of the equipment and affected interior patient compartment of the ambulance or other affected portions of the vehicle until wet. Wait 30 seconds and wipe dry with a paper towel. To kill staph, strep, and other common types of virus and bacteria strains, repeat as above, wait 10 minutes, and wipe dry. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.
- D. **Steps in cleaning after each transport:**
  - 1. Remove gurney.

2. All visible debris and soil contaminants are wiped off with towels.
3. Cleaning agent mixture is sprayed liberally on the interior of the transport compartment of the vehicle.
4. Cleaning agent mixture is sprayed liberally on the gurney mattress, the gurney frame, including wheels.
5. All surfaces are inspected to ensure that no visible signs of debris, soil, or contaminants are present; if such signs still exist, then repeat the cleaning process.
6. Towels are disposed of appropriately for washing. Paper towels must be placed in a red or properly marked biohazard bag or container if blood-soaked; otherwise, they may be treated as normal trash per Scottsdale Health Care SOGs.
7. Gloves must be placed in a red or properly marked biohazard bag or container if blood-soaked; otherwise, they may be treated as normal trash per Scottsdale Health Care SOGs.

## **II. Special Equipment Cleaning Instructions**

- A. Patient restraint straps (spine board, gurney); remove immediately when contaminated with blood or body fluids or body substances/secretions and place in a red or appropriately marked biohazard bag.
  1. Straps are washed upon return to the station in an appropriate detergent according to manufactures instruction and recommendations.
  2. Air or machine dry as recommended.
- B. Equipment bags made of Cordura nylon; remove from service immediately when contaminated with blood, body fluids, or body substances/secretions and place in a red or appropriately marked biohazard bag.
  1. The bags will be washed upon return to the station in appropriate detergent according to manufacturer instructions and recommendations.
  2. Air or machine dry as recommended.
- C. MAST/PASG: Before washing, all gauges are removed, using the quick-disconnect tubing and closing all valves. Washing is done by hand in soapy water. **DO NOT DRY CLEAN, BLEACH, STEAM CLEAN, OR USE HARSH CHEMICALS. FOLLOW MANUFACTURERS INSTRUCTIONS.**
- D. Laryngoscope blades and Magill forceps, portable suction units (and any other nondisposable instruments that touch mucous membrane): equipment is cleaned with the cleaning agent mixture ensuring complete coverage with the agent mixture and then rinsing. Ensure that all needles and contaminated scalpels are placed in a sharps container
- E. The radio equipment should be decontaminated by spraying cleaning agent on a towel and wiping down the portable radio and microphones/mobile radio.
- F. Turnouts that have been contaminated should be removed from the individual, bagged in a red bag or appropriate biohazard container, and taken to the station. The turnouts should be first hosed off and brushed using liquid detergent that does not have any chlorine products. Once hosed off, the coat and pants should be separated from the liner (if possible) and placed in a washing machine with soap and hot water. The turnouts and liners should be air-dried. The washing machine should be cleaned using a 10% mixture of bleach and run through a complete cycle.

## APPENDIX B: Sample Exposure Control Plan

### North Dakota Ambulance Service

#### **Exposure Control**

##### **DISCLAIMER**

*The protocols developed by the North Dakota Department of Health are meant to be used as general guidance for developing protocols for individual emergency medical services agencies. These sample protocols are not meant to be medical or legal advice; nor do they establish standards of care. Each emergency medical services agency must tailor protocols based on their specific needs or capabilities. Local medical directors must be consulted with and approve any protocol(s) prior to becoming operational in an emergency medical services agency.*

Ambulances will be following the Occupational Safety and Health Administration (OSHA) standards to limit occupational exposure to blood and other potentially infectious materials since any exposure could result in transmissions of bloodborne pathogens which could lead to disease or death. Each member of the staff will receive training at least annually about the information contained in this plan and will be expected to follow the procedures outlined and use the equipment provided. Any questions should be referred to management.

#### 1. POTENTIAL INFECTIOUS PLACES AND/OR MATERIALS

- a. Semen
- b. Vaginal secretions
- c. Cerebrospinal fluid
- d. Synovial fluid
- e. Pleural fluid
- f. Pericardial fluid
- g. Peritoneal fluid
- h. Amniotic fluid
- i. Saliva
- j. Any body fluid visually contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids
- k. Any unfixed tissue or organs other than intact from a human (living or dead) and HIV cells or tissue cultures

**\*\*All personnel working on ambulance crews and first responders are at risk for exposure to blood and bodily fluids.**

#### 2. Possible areas in the workplace that could be contaminated with bloodborne pathogens:

- a. Every call could be potential for contamination, therefore it is mandatory that all safety precautions be taken when doing patient care (universal blood precautions).
- b. Cleaning inside patient care area of ambulance, safety precautions must be followed (universal blood precautions).
- c. When cleaning any patient care equipment, safety precautions must be followed (universal blood precautions).

3. Personal Protective Equipment that will be provided:
  - a. Nonsterile latex-free gloves.
  - b. Gowns
  - c. Goggles
  - d. Masks
  - e. Sharps disposal system
  - f. Fluid absorbent, dust pan, and whisk broom
  - g. Small resealable plastic bags
  - h. Hand cleaner
4. Universal Precautions
  - a. Nonsterile gloves will be used when handling body fluids, secretions, and excretions as well as articles contaminated with them. Gloves shall be worn when in contact with mucous membranes and nonintact skin.
  - b. Hands shall be washed immediately if they are in contact with blood or body fluids and after completion of each call. Hand sanitizer is a waterless product located in all rigs for times when soap and water washing are not available. Wash your hands with soap and water as soon as you get the opportunity after using the approved hand sanitizer.
  - c. Gown if soiling is anticipated with blood and/or body fluids, secretions, or excretions.
  - d. Goggles, if splashing of blood and/or body fluids is anticipated.
  - e. Mask, if sustained contact with patient who is coughing extensively, for intubated patients being suctioned, or if splashing of blood and/or body fluids is anticipated.
  - f. Dispose of sharps in receptacles. Only recap needles by using one hand to hold the base of the needle as you slide it back into the protective cap. Do not stick your hand or fingers in a sharps container or place garbage in a sharps container.
  - g. Do not eat, drink, smoke, apply makeup or lip balm, or adjust contact lenses in the patient compartment of the ambulance.
5. HBV immunizations
  - a. The service will provide hepatitis B immunizations to all team members.
  - b. The service will also provide annual education on precautionary measures, epidemiology, and modes of transmission and prevention of HIV/HBV.
  - c. Immunizations should be started within ten (10) working days of employment, unless the team member refuses or has medical documentation that states that the team member does not need the immunization.
6. Types of significant exposure:
  - a. Contact with your nonintact skin (i.e., rash, lesion, open/healing wound, etc.).
  - b. Contact with your eyes.
  - c. Contact with your mouth, nose, or mucous membranes.
  - d. Puncture or penetration of your skin by any contaminated object.
7. Nonsignificant exposures:
  - a. Contact with intact skin.
  - b. Contact with clothing that does not soak through.
8. Steps to follow when exposed to body secretions:
  - a. Fill out an incident report to include: (a) name of patient; (b) any precautions that were taken at time of injury.
  - b. Fill out an exposure form at the hospital.

- c. Wait for report that will tell you if you need to be tested.
  - d. If testing is needed, contact your supervisor.
  - e. Copies of all reports must be kept on file at the facility. (These files will be kept confidential.)
  - f. If you test positive for HIV or HBV you can go to the hospital for counseling. All testing should be done as soon as possible or within 24 hours of the exposure.
  - g. Any time contact is made with a patient with a communicable disease, notify the operations supervisor so he/she can contact other responders.
9. Instructions for Exposed Materials:
- a. Contaminated disposable items will be placed in a red garbage bag in the ambulance or at the hospital.
  - b. Reusable equipment will be disinfected. Laryngoscope blades and stylettes shall be cleaned with soap and water, placed in approved cleaner for ten (10) minutes, and washed with soap and water again.
  - c. Soiled linen shall be placed in red bags. Normal bed linen can go to the cleaners.
  - d. Contaminated clothing shall be placed in red bags and taken to the cleaners. Do not take visibly contaminated clothing home to be washed.
10. Ambulance Decontamination
- a. In the event the ambulance is used to transport a patient with a known communicable disease, or the ambulance becomes contaminated with blood or bodily fluid, the unit will be taken out of service after the transport to be cleaned.
  - b. Materials to use for cleaning:
    - i. Spray cleaner (e.g., Hepacide<sup>®</sup> and BH38)
    - ii. Sani Wipes<sup>®</sup>
    - iii. Towels
    - iv. Gloves
    - v. Chlorasorb
    - vi. Broom and dustpan
  - c. Procedures for cleaning:
    - i. Spray all surfaces then wipe.
    - ii. Remove all linen and place in the red garbage bags.
    - iii. Use Chlorasorb or other fluid absorbent if needed to clean up large or small amounts of blood, vomit, urine, etc.
    - iv. After each call the ambulance shall be inspected for bodily fluids and general contaminants. If you suspect contamination, Hepacide or other cleaner shall be used to disinfect the soiled areas. BH38 may be used for general cleaning.
  - d. High Level Decontamination: Hepacide
    - i. Should be done once per month, and will be total ambulance decontamination.
    - ii. Any time bodily fluids cause a biohazard in the unit, the area or equipment will be decontaminated.
  - c. Low Level Cleaning: BH-38
    - i. General cleaning of the unit of soil or as needed.

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*Medical Director's Signature*

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*Date*

## APPENDIX C

### Definition of Terms

#### ***OSHA - Occupational Safety and Health Administration***

##### **U.S. Department of Labor**

- Bloodborne pathogens. - 1910.1030
- Regulations (Standards - 29 CFR) - Table of Contents
- Part Number: 1910
- Part Title: Occupational Safety and Health Standards
- Subpart: Z
- Subpart Title: Toxic and Hazardous Substances
- Standard Number: 1910.1030
- Title: Bloodborne pathogens.
- Appendix: A

1910.1030(a) ***Scope and Application.*** This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

1910.1030(b) ***Definitions.*** For purposes of this section, the following shall apply:

***Assistant Secretary*** means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

***Blood*** means human blood, human blood components, and products made from human blood.

***Bloodborne Pathogens*** means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

***Clinical Laboratory*** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

***Contaminated*** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

***Contaminated Laundry*** means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

***Contaminated Sharps*** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.



**Decontamination** means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Director** means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

**Engineering Controls** means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

**Exposure Incident** means a specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

**Fomites** is an inanimate object or substance, such as clothing, furniture, or soap, that is capable of transmitting infectious organisms from one individual to another.

**Hand Washing Facilities** means a facility providing an adequate supply of running potable water, soap, and single-use towels or hot air drying machines.

**HBV** means hepatitis B virus.

**HIV** means human immunodeficiency virus.

**Licensed Healthcare Professional** is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Postexposure Evaluation and Follow-up.

**Needleless systems** means a device that does not use needles for: (1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

**Occupational Exposure** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

**Other Potentially Infectious Materials** means (1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

**Parenteral** means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

**Personal Protective Equipment** is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

**Production Facility** means a facility engaged in industrial-scale, large-volume, or high concentration production of HIV or HBV.

**Regulated Waste** means liquid or semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

**Research Laboratory** means a laboratory producing or using research laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

**Sharps with engineered sharps injury protections** means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

**Source Individual** means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

**Sterilize** means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

**\*\*Universal Precautions** is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

**Vector** is an organism, such as a mosquito or tick that carries disease-causing microorganisms from one host to another.

**Work Practice Controls** means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by technique).

**\*\*Although OSHA still uses the term Universal Precautions and focuses mainly on blood exposures, many EMS systems use the more common term Standard Precautions.**

**Standard Precautions** are based on the principle that all blood, body fluid secretions, excretions except sweat, nonintact skin, and mucous membranes may contain infectious diseases. Implementation of Standard Precautions constitutes the primary strategy for the prevention of healthcare-associated transmission of infectious agents among patients and healthcare personnel.

# APPENDIX D

## Acronyms and Abbreviations

**ARO** - Antibiotic-resistant organisms

**CDC** - The Centers for Disease Control and Prevention

**DICO** - Designated Infection Control Officers

**ECP** - Exposure Control Plan

**EMT** - Emergency medical technicians

**EMS** - Emergency Medical Services

**EPA** – Environmental Protection Agency

**FOG** - Field Operations Guides

**HBV** – Hepatitis B virus

**HCV** – Hepatitis C virus

**HHS** – U.S. Department of Health and Human Services

**HIPAA** - Health Insurance Portability and Accountability Act

**HIV** - Human immunodeficiency virus

**IP** - Infection preventionist

**MDRO**- Multidrug-resistant organism

**MRSA** – Methicillin-resistant *Staphylococcus aureus*

**MSDS** - Material Safety Data Sheets

**NIOSH** - The National Institute for Occupational Safety and Health

**OPIM** - Other potentially infectious materials

**PPE** - Personal protective equipment

**SARS** - Severe acute respiratory syndrome

**SNS** - Strategic National Stockpile

## Legal Issues

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### Abstract

*Lawsuits against healthcare providers typically involve both civil actions against an organization and professional malpractice suits against physicians and other healthcare practitioners that work at the organization. The fear of litigation is the primary reason practitioners pay attention to standards, state rules, and federal laws that govern their practice. The specialty of infection prevention brings to light many issues that have both legal and ethical implications that should be considered in any decision-making process.*

### Key Concepts

- The legal nature of infection prevention issues.
- The laws and legal cases that set the precedent for determining the outcome of a legal issue.
- The ethical situations that arise in healthcare and involve infection preventionists.
- The importance of effective infection prevention and control and risk management programs.
- Analyze the changing legal climate and the activities that infection preventionists must perform to reduce the likelihood of a legal matter.
- Organizational leaders' responsibility and role in reducing the risk and liability for themselves and for the organization.

### Background

The Centers for Disease Control and Prevention (CDC) estimates that 1 of every 10 to 20 patients hospitalized in the United States develops a healthcare-associated infection (HAI). Healthcare institutions

have for some time focused infection prevention efforts on monitoring patient clinical outcomes and finding ways to prevent HAIs. Recently, healthcare organizations, professional associations, government and accrediting agencies, legislators, regulators, payers, and consumer advocacy groups made HAIs a national priority. Evidence-based practice recommendations for detecting and preventing HAIs contain ways to assist acute care hospitals with implementing and prioritizing their HAI prevention efforts. Hospitals routinely focus their work on central line-associated bloodstream infections (CLABSIs), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infections (CAUTIs), and surgical site infections (SSIs). In addition, two organism-specific HAI categories, methicillin-resistant *Staphylococcus aureus* (MRSA) infection and *Clostridium difficile* infection (CDI), command prevention efforts because of the increasing incidence, morbidity, and legal actions associated with acquisition of these organisms in the acute care setting and in the community at large.

Because of the shift from control to prevention, the Association for Professionals in Infection Control and Epidemiology (APIC) announced a scope change from infection control practitioners to infection preventionists, who take responsibility to implement policies and procedures that reduce or prevent HAIs. The change in title to an *infection preventionist (IP)* reflects the broad array of responsibilities that these professionals have, such as ensuring that the organization and its employees follow established standards of care to protect employees, patients, and patients' family members from exposure to infection and to maintain an environment of safety and protection from injury. In order to do so, IPs must ensure:

1. Accurate and complete documentation reflects the care provided.
2. Organizations implement and monitor compliance with National Patient Safety Goals.
3. Organizations maintain patient and employee confidentiality.
4. Organizations develop clear policies and systems to control and prevent the spread of infection from healthcare personnel to patient and vice versa and to the community.
5. The infection prevention department works in concert with the risk management and quality assurance departments.

The IP becomes integral and often leads the efforts in emergency management, bioterrorism, construction and renovation projects, and planning for pandemic outbreaks. The emergence of community infections and chronic infections also presents unique challenges for the IP who requires continued training to meet inpatient and community needs.

When an issue of potential liability arises, organizations should consult with legal counsel to assure an accurate account of the findings in the matter. Resolution of legal issues usually depends on whether state or federal law applies to the situation, and in the absence of written statutes, whether a preceding case decision has set the legal precedent.

## Basic Principles

In general, rules create laws that govern the behavior of individuals in this country. These rules may surface in the form of federal and state constitutions, statutes, administrative laws, written court decisions, and case law. When written statutes do not apply in a particular case, or when case precedent does not exist, the court decides the law. Common law is the law created when there is no statute governing a particular situation at hand.

A constitutional right, a statute, or common law creates a legal *cause of action*. A cause of action has several elements. Attorneys must prove each element before the plaintiff (the person on whose behalf

the suit is filed) can establish legal liability on the part of the defendant (the person being sued).

In general, for a person to bring a cause of action against another, the following elements must exist:

- The plaintiff must have an interest that is protected by law.
- The plaintiff must show the defendant had a legal duty to act.
- The plaintiff must prove the defendant breached the duty to act.
- The plaintiff must show injury or damage to the protected interest.
- The plaintiff must prove that the defendant's breach of duty caused the injury.

Initially, the burden of proof rests with the plaintiff. The plaintiff's case must establish a burden of proof by a preponderance of the evidence. If the plaintiff succeeds in establishing proof, the burden of proof shifts to the defendant. If the plaintiff establishes liability, the plaintiff must then prove damages. In some cases, the court may decide there are no material fact issues and that the required elements of the cause of action do not exist or that a legal defense exists. In these cases, the court grants summary judgment in favor of the prevailing party without a trial.

Medical malpractice is legally defined as >professional negligence by act or omission by a healthcare provider in which the treatment provided falls below the accepted standard of practice in the medical community and causes harm to the patient. Physicians generally obtain professional liability insurance to offset the risk and costs of lawsuits based on medical malpractice. Other healthcare providers can also procure their own professional liability insurance but most do not because of the high cost of the insurance coverage and rely solely upon the general liability coverage provided by their employer. The medical malpractice cases filed in the legal system generally seek large amounts of monetary compensation, and no matter how small or large the claim, the cost of defending the claim impacts healthcare professionals and the healthcare organization involved. Large monetary awards in medical malpractice cases that proceed to a jury trial receive notoriety that in turn encourage the filing of medical malpractice claims by others, thus perpetuating the cycle of litigation that impacts the cost of delivery of healthcare and threatens the overall accessibility, affordability, and quality of healthcare in this country.

A person acts negligently if he or she departs from the conduct expected of a reasonably prudent person acting under similar circumstances. Departure from reasonable conduct may take the form of an omission or commission of an act. Omission of an act includes:

- Failing to administer medications.
- Failing to order diagnostic tests.
- Failing to follow up on abnormal test results.

Commission may include:

- Administering the wrong medication to a patient.
- Administering medication to the wrong patient.
- Performing a surgical procedure without patient or family consent.

For a plaintiff to recover damages resulting from a negligent act, the plaintiff must address the following four elements.

1. Duty: an obligation to conform to a recognized standard of care.

2. Breach of duty: a deviation from the recognized standard of care.
3. Causation: an act or conduct departing from the recognized standard of care that caused injury.
4. Injury: the result of the deviation from the recognized standard of care

To illustrate negligence, consider an example of a patient who acquires an infection during his or her hospital stay. The patient must establish:

1. He or she contracted an infection in the hospital.
2. The hospital, through an act of negligence, breached its duty to the patient and did not follow a policy or procedure to prevent the infection.
3. The hospital's negligence caused the infection.
4. The patient's condition worsened because of the infection.

The test for negligence in this example rests on whether the hospital care or lack of care caused the infection and whether the hospital and the personnel working with the patient acted in a reasonable and prudent manner to recognize, report, and try to control the infection.

## CAUSATION, DAMAGES, AND LIABILITY

To prevail in a negligence action, the patient must prove that the hospital's failure to exercise a required standard of care directly caused the plaintiff's injury. The plaintiff proves the act or omission of the act resulted in the immediate damage without intervention of another party. This is referred to as the *proximate cause*. If the patient's attorney can establish that their plaintiff client experienced injury due to an infection resulting from the hospital or staff negligence, the hospital or its staff may be liable.

Liability is not established on mere proof that a patient developed an infection. Because HAIs are common, unpredictable, and sometimes difficult to prevent, courts have recognized that such infections may occur despite reasonable care. For example, in *Simmons v. United States*, a patient developed an abscess around an intravenous needle site. The court stated that proper prophylactic care (such as using a sterile needle and frequent dressing examination and change) does not eliminate the possibility of developing an infection. Hospital employees, therefore, must be alert to infections and immediately report suspected infections to the physician.

A provider may not be liable for infection sustained by a patient who is more susceptible to infection than the average patient. For example, in the 1994 case *Lawlor-Covell v. Wack, M.D.*, a leukemia patient with a decreased white blood cell count died of an infection. The patient's family alleged that the patient contracted the infection due to the negligence of a hospital worker who did not adhere to the hospital's infection prevention policies. However, the jury found that the defendant did not act negligently and rendered its verdict on behalf of the hospital. Because of difficulty establishing that a particular act or omission specifically resulted in infection, patients are rarely awarded damages for hospital-associated infections. However, as methods of detecting microorganisms improve, the ability to trace the specific sources of infections, thereby proving proximate causation, also improves.

## PROVIDER DEFENSES TO NEGLIGENCE

Despite a patient's ability to establish all required elements for medical negligence, the healthcare provider can raise affirmative defenses that, if proven, excuse the healthcare provider from liability. An affirmative defense is a response to a plaintiff's claim that attacks the plaintiff's *legal right* to bring an action, as opposed to attacking the truth of the claim. Examples of affirmative defenses include: (1) the statute of limitations, (2) assumption of risk, (3) contributory negligence, (4) release/waiver, and (5) any other matter that constitutes avoidance. These legal approaches can eliminate or reduce liability even if



the plaintiff can establish all the necessary elements of a cause of action. The statute of limitations prevents the plaintiff from initiating a lawsuit after a statutorily defined period of time has elapsed. The assumption-of-risk defense prevents a recovery of damages when the plaintiff perceives a risk and still voluntarily exposes him- or herself to the risk. Contributory negligence arises when the plaintiff fails to exercise ordinary care and self-protection, thereby contributing to the injury. A release or waiver executed by a patient may relieve the defendant of liability for the results of subsequent treatment. Other defenses that may excuse a defendant from liability include Good Samaritan (charitable immunity) statutes, workers' compensation, and government immunity.

## THEORIES OF LIABILITY

Liability can be imposed on any healthcare provider, including hospitals, physicians, and nurses. According to the CDC, an estimated 2 million cases of nosocomial infections (now known as HAIs) occur annually. Hospital liability for negligence relating to an HAI arises from two different theories. The first theory is that negligence arises from the behavior of one or more employees or agents. According to the California 4th Appellate Court case *Sababin v. Superior Court (Covina Rehabilitation Center)* (2006), the appellate judge concluded that the trial issues were whether Covina's employees acted recklessly or with malicious neglect. The court found that employees failed to follow the patient's care plan for maintaining the health and integrity of the patient's skin. The appellate court remanded the case to the trial court asking that the court consider Covina's argument that it was not liable for its employees' conduct.

The second theory holds that a hospital corporation itself may be negligent if the hospital corporation fails to perform a legally recognized duty to protect the patient from harm. If a staff physician, resident, nurse, or other hospital employee is negligent with respect to a patient, negligence may be imputed to the hospital, and the patient may have a cause of action against both the employee and the hospital-employer. Even if an employer is found to be liable under the principle of agency, the employee who actually committed the act can also be held personally liable for his or her actions or failure to take action. A patient may sue any one party separately or all of them collectively.

## DUTY TO PROVIDE CARE

To establish a case of negligence, the plaintiff must prove that he or she had a patient/provider relationship with the defendant, and that the defendant had a duty or obligation of performance to provide care. Duty may arise from a relationship that exists between the doctor and the patient or the nursing staff and the patient to protect the patient from harm or injury. In the healthcare context, a duty translates to a *standard of care*. Once patients place themselves under a healthcare practitioner's care, the practitioner has a duty to provide the patient with *reasonable* care. A duty of care corresponds with the responsibility not only to provide care or treatment but to do so in an acceptable manner.

To prove negligence, the patient must establish that the hospital failed to meet a standard of care. The standard of care depends on the circumstances of the particular case and often attorneys disagree in the determination of the applicable standard of *reasonable* care in a specific situation. Further, attorneys must determine whether the physician, nurse, other staff members, or the hospital breached the standard of care.

Whether a patient outcome meets the definition of negligence depends on whether care practices conform to the standards of other providers in the same locality. Under this customary practice standard rule of the local community, or locality rule, the legal community measures the provider's performance against the level of care delivered by reasonably competent persons, or institutions, of equivalent skill in the same or similar geographic community. Thus, the legal society concentrates on collecting evidence



to determine whether or not the provider did something unc customary or failed to do something that was customary practice.

Today, most states have substituted the locality rule in favor of a more national standard of care. The national approach assumes evidence-based practice to result in one prevailing level of care. Experts may frequently disagree about what constitutes appropriate safe care or best practice in specific situations. The disagreement, diversity, or lack of standardization causes a variety of approaches that define the standard of care for a given clinical situation. Thanks to efforts from national leaders such as the National Quality Forum (NQF), Agency for Healthcare Research and Quality (AHRQ), Institute of Medicine (IOM), and The Joint Commission (TJC), "best practice" standards have emerged for healthcare organizations. Organizations that institute national standards can compare their results with other similar organizations and with national benchmarks.

When a person alleges that a healthcare provider fails to meet a standard of care, the person must first establish the standard and then prove the organization or individual breached the standard. This proof normally comes from expert testimony. Alternatives to expert testimony include use of medical texts, journals, state and federal laws, regulations, and guidelines, protocols, and practice parameters.

## PRACTICE PARAMETERS

Hospitals and other healthcare institutions have the arduous task of caring for patients with complex medical conditions and comorbidities such as chronic diseases and antibiotic-resistant infections. The American Medical Association (AMA) and TJC support the development and implementation of practice parameters. Practice parameters, or practice protocols, are medical guidelines that encompass a broad range of strategies designed to assist practitioners in the clinical decision-making process. More specifically, they are standardized specifications for care developed through a formal process that incorporates the best scientific evidence of effectiveness with expert opinion. Medical professionals in specific areas set these guidelines in order to advise colleagues of the recommended standard of care to use in a given situation. For example, the goal of practice parameters established by the Agency for Health Care Policy and Research (AHCPR), a federal agency empowered to establish practice parameters, is to encourage physicians and other healthcare providers to change their practice behavior by adopting guidelines, thus improving patient care, patient outcomes, and quality of life.

Practice parameters assist healthcare facilities to meet national quality indicators. In 1998, the Centers for Medicare & Medicaid Services (CMS) developed 24 quality indicators to improve care delivered in skilled nursing facilities and nursing homes. Quality indicators include reducing the incidence of falls and infections, reducing the rates of pressure ulcers, and eliminating incidents of dehydration. Practice parameters, also called protocols, clinical pathways, or care maps, serve as tools that guide a practitioner in the care of a particular condition. Practice parameters often include strategies to meet a specific quality indicator. Practice parameters allow for variances in the patient's condition and take into account the comorbidities of a patient's condition.

Practice parameters are not absolute rules of conduct. Because compliance is voluntary, most practice parameters include incentives for physicians, healthcare institutions, and healthcare workers. Incentives may include full reimbursement for care, reduced length of stay in a hospital, national recognition from accreditation associations, higher patient satisfaction, lower risk management premiums, and fewer survey enforcement activities from state and federal regulators. Such incentives help shape the conduct of physicians, institutions, and other healthcare personnel, thereby improving patient care, patient outcomes, and quality of life. The diversity of interests participating in the practice parameters movement contributes to the standard of practice momentum. Active participants, such as state

governments, private healthcare researchers, third-party payers and health benefit plan sponsors, medical specialty societies, and voluntary health organizations, drive the standardization concept that improves the quality, safety, and affordability of medical care.

## STANDARD OF CARE IN HEALTHCARE-ASSOCIATED INFECTION CASES

Although hospitals have a duty to protect patients from injury due to infections, courts never maintain that organizations guarantee that patients will not acquire an infection while in the institution. However, organizations must realize that the potential of liability exists if a patient's infection results from negligence of its physicians or employees.

To determine a standard of care, organizations must monitor patient outcomes. At a minimum, monitoring includes conducting quality assurance activities such as: performing infection surveillance; reviewing and revising infection prevention policies and procedures; providing in-service training sessions for staff about appropriate infection prevention practices; and adhering to the National Patient Safety Goals (NPSGs). Two NPSGs that relate to infection prevention include compliance with the hand hygiene guidelines and managing identified cases of unexpected death or major permanent loss of function associated with HAIs as a sentinel event.

If a patient establishes that he or she acquired an infection at a hospital, the hospital may have to prove infection prevention policies and practices were in place and that the physician and staff took immediate and appropriate interventions to treat and minimize the patient's infection. To ensure that the hospital meets its standard of care, the hospital should continuously evaluate how staff use aseptic technique and follow infection prevention procedures. Organizations should monitor with consistency through direct observation of staff performance to validate proper compliance. The organization should make sure that all members of the healthcare team follow state and federal infection prevention regulations, accreditation standards, and practices and procedures. In addition to staff compliance with infection prevention practices, organizations should establish clear, useful internal practice manuals that are readily available to all staff members.

Accreditation requirements, federal and state laws, and regulations provide an organization with established standards of care. In some instances, the standard of care serves as a substitute for expert testimony. In most states, organizations are subject to government rules regulating the practice of infection prevention. Program requirements vary considerably from state to state; thus, healthcare leaders and legal counsel should consult their own state's regulations. Some states allow considerable latitude in procedures, providing little guidance. Other states, such as Illinois, set forth explicit requirements for infection prevention procedures, including requirements for the sterilization of equipment, instruments, utensils, water, and supplies. Some state laws and regulations even specify the particular methods of sterilization to be used. Courts have sometimes ruled that these regulations establish guidelines for minimum standards of hospital care. However, mere compliance with minimum statutory or regulatory standards and licensure provisions may not preclude an organization from liability. Courts may hold organizations to a higher standard due to local practices.

## Strengthening Practices to Reduce Potential Liability

To reduce the risk of liability, an organization should concentrate on basic documentation practices that clarify what happens to a patient during his or her inpatient stay. Accurate, complete, timely, and appropriately detailed documentation becomes significant in legal matters and may reduce organizational liability.

## PUBLIC REPORTING

Since 2002, a few states have enacted legislation that requires healthcare organizations to publicly disclose HAI rates. Similar legislative efforts are under way in several states, including Kentucky. Advocates of mandatory public reporting of HAIs believe that making such information publicly available will enable consumers to make more informed choices about their healthcare. Advocates also believe public reporting of HAIs reduces incidents of infections and improves overall healthcare quality. For example, consumer safety advocate organizations spearheaded a program for hospitals in the early 1990s to publish information about deaths arising from coronary artery bypass graft surgery. That effort caused hospitals and surgeons to look at their current practice and make changes to their practices, which dramatically lowered mortality rates. Consumer safety groups today draw an analogy to the 1990s results, hoping that HAI reporting will cause a similar outcome.

Consumer safety advocate groups believe that patients have a right to know an organization's infection rates, whereas other groups express concern about the reliability of public reporting systems because of the variability in system definitions of HAIs, or in the methods and resources used to collect HAI data. The challenge for organizations to collect infection data occurs because of an absent standard method for counting what actually constitutes an HAI. For example, a hospital may not know if the patient acquired an infection before, during, or after a hospital stay. Because of infection-detection difficulties, most hospitals choose to monitor procedural outcomes, which account for the majority of infections. Mandatory collection of data, especially on a hospital-wide scale, can be quite costly and an administrative burden for the organization.

A voluntary reporting system, relying on incentives to organizations choosing to share data, would encourage organizations to track only the most important infection types and allow atypical organizations to opt out of reporting. Public reporting of these data may also have negative repercussions. The organizations that most diligently report infections will appear to be the least safe, and public reporting may also provide incentive for organizations to turn away marginal cases. Concerns also arise if organizations receive a poor report card. Leaders fear less-than-desirable outcomes might be used against the organization or practitioner in legal proceedings. A confidential report, made to an agency with oversight capabilities, is one alternative to public reporting.

The CDC's Healthcare Infection Control Practices Advisory Committee set policy guidelines in 2005 that suggest counting HAIs using public health surveillance methods, creating oversight councils, and allowing institutions to preview their data before state agencies make the data public record. Today almost every state has either passed or attempted to pass a bill making national public reporting inevitable.

## A NATIONAL REPORTING SYSTEM: NSHN PROGRAM GOALS AND REQUIREMENTS

In the early 1970s, the CDC developed the National Nosocomial Infections Surveillance (NNIS) system to monitor the incidence of HAIs or nosocomial infections. The Web-based successor to NNIS, the National Health Safety Network (NHSN), also a voluntary and confidential system, assists a reporting hospital with releasing data to organizations such as state or local health departments and quality improvement organizations. NHSN is the only national system that can track HAIs and allow voluntary reporting of infections. Many hospitals use NHSN today. The CDC developed the NNIS system to help infection prevention professionals and hospitals stay abreast of the rapidly expanding science and practice of infection prevention and better manage endemic and epidemic episodes of HAI. The principles of the NNIS and NHSN systems are based on CDC's definition of public health surveillance

and are divided into the following four objectives: (1) detect and monitor adverse events; (2) assess risk and protective factors; (3) evaluate preventive interventions; and (4) provide information to stakeholders and partner with them to implement effective prevention strategies. Organizations use the NHSN database to:

- Describe the epidemiology of HAIs.
- Describe antimicrobial resistance associated with HAIs.
- Produce aggregated HAI rates suitable for interhospital comparison.

The CDC requires hospitals participating in NHSN to have sufficient infection prevention personnel to collect the data using standardized protocols and numbers of beds to yield enough cases of HAI for reliable estimation of the incidence and trends over time. The CDC collects data on HAIs for research and investigation, as authorized under Title III, Section 301, Section 304, and Section 306 of the Public Health Service Act (42 USC 241, 242b, 242k, and 242m[d]). Because of the sensitive nature of the data, the NHSN system guarantees confidentiality for the identity of both the patients and the reporting hospital. The CDC analyzes, interprets, and publishes reports of aggregated data but cannot release any patient-specific data or any hospital-specific data without written consent of the participating hospital. Hospitals may voluntarily release their own NHSN data to anyone they choose.

## DOCUMENTATION

Incomplete or inaccurate documentation can open an organization or individual up to a whole host of legal actions. Many courts decide the outcome of a legal action or regulatory citation on what is or is not documented in the patient's medical record. Therefore, healthcare facilities must educate employees about the processes and policies in place that promote accurate and comprehensive documentation of patient care. The organization should regularly perform open and closed medical record reviews for presence of the following:

- Clear and complete physician orders. Medication orders that include the name of the medication, therapeutic dose, time administered, route, start and stop dates, and any specific parameters for contacting the physician or withholding the medication. When a physician issues a verbal order to a practitioner, the practitioner must always immediately write down the order, read the order back to the physician, and verify with the physician that the order is correct.
- Complete documentation of the medication reconciliation process and patient and family education.
- Physicians, nurses, and other members of the healthcare team date and time their entries into the medical record and legibly sign their entries.
- The medical record contains a clear account of the patient's condition, including any change in condition, response to treatment, ongoing assessments such as the patient's response to pain, and a safety assessment.
- The documentation addresses the medical plan of care and any changes or updates to the care plan, including any decisions the patient makes about his or her care.
- The documentation supports collaboration between disciplines, including outside agencies.
- The medical record contains clear and effective communication between staff members, other disciplines, and the patient's family.
- A factual description of any event, such as a patient fall or injury, along with appropriate safety measures in place to prevent the event from recurring.



## LEGAL ISSUES OF AN ELECTRONIC HEALTH RECORD

In an effort to ensure patient safety, most organizations have implemented all or part of an electronic health record (EHR) system. Whether an organization buys an entire EHR system, builds and customizes their own EHR, or uses a hybrid system, EHRs can improve communication between providers about the patient's plan of care. An EHR refers to an individual patient's medical record in digital format. EHR systems coordinate the storage and retrieval of individual records accessed on a computer over a network. Organizations should follow security rules and take proper safeguards in the release of electronic data. Recent federal government initiatives support using EHRs to:

- Connect clinicians so that they can exchange health information using advanced and secure electronic communications;
- Personalize care with consumer-based health records and better information for consumers; and
- Improve public health through advanced bio-surveillance methods and streamlining of the collection of data for quality measurement and research.

## PATIENT SAFETY

Everyone in a healthcare institution must take responsibility to assure patient safety. Ensuring patient safety includes:

- Furnishing and maintaining proper equipment, supplies, and services and exercising reasonable care in the selection and use of such equipment, supplies, and services.
- Exercising reasonable care in the selection and retention of appropriate personnel.
- Exercising reasonable care with respect to the maintenance of buildings and grounds, including keeping the environment clean and sanitary with the aim of preventing infection.
- Complying with policies and procedures, whether established by the institution or outside agencies that have as their objective the safety and well-being of patients and the public.

TJC announces NPSGs annually that healthcare organizations must meet in order to maintain accreditation status. Because an NPSG addresses the organization's obligation to establish processes, policies, and procedures to protect patients from infections, institutions that fail to establish proper procedures and techniques of infection prevention have potential liability when an adverse patient outcome occurs that is related to an HAI. In addition, hospitals may have a duty to monitor specific infection rates and to intervene immediately if institutional leaders or the IP notices excessively high infection rates.

TJC mandates the presence of an effective institution-wide program for the surveillance, prevention, and control of infection. Characteristics of an effective infection prevention and control program include written policies and procedures for infection surveillance, and strategies to prevent and control the spread of infection to patients, patient care departments, and service areas. Medicare conditions of participation for hospitals constitute federal regulations for hospital infection prevention and control programs and mandate that hospitals provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.

Physician responsibilities for infection prevention include ensuring appropriate clinical care, serving as a member of the hospital's infection prevention committee, or serving as a hospital epidemiologist or infection prevention officer. In general, physicians act as a role model for medical asepsis. Physicians may incur liability for failing to adhere to appropriate infection prevention standards of care. In addition, as the availability of physicians specializing in infectious diseases grows, liability could result for a

physician who fails to consult with an infectious disease specialist about a patient with an infectious process.

## COMPLIANCE STRATEGIES FOR PATIENT SAFETY AND REDUCING THE RISK OF INFECTION

Each organization should review the NPSGs and associated recommendations and determine how best to comply with each of them. Ensuring patient safety makes good business sense and will help organizations manage risk. Healthcare organizations are required to establish and maintain infection prevention and control programs that provide a safe, sanitary, and comfortable environment for patients. The infection prevention and control program should focus on preventing infection and reducing the risk and transmission of infection among patients, visitors, and staff members. Elements of the program include:

- Creating a prioritization matrix to determine the top opportunity for improvement that reduces the volume of infections or reduces the severity of patient infections and prevents the spread of infections.
- Creating an infrastructure that eliminates the barriers between infection prevention and risk management and quality management.
- Selecting initiatives and developing a practical action plan that uses principles of performance improvement.
- Developing a strategic plan that identifies how to change successful strategies into worthwhile gains.
- Ensuring healthcare personnel comply with hand hygiene guidelines to prevent cross-contamination.
- Preventing a patient's exposure to contagious organisms.
- Ensuring housekeeping efforts follow guidelines for proper cleaning, sterilization, and handling of equipment.
- Ensuring healthcare personnel have protection from exposure to infectious diseases.
- Conducting surveillance of personnel, reviewing immunization records, and providing employees with immunizations if necessary.
- Ensuring that the ethical issues in infection prevention, including the sensitive nature of sexually transmitted diseases, are addressed.

## CREATING THE INFRASTRUCTURE, MATRIX, PRIORITIZING, AND DEVELOPING A STRATEGIC PLAN

Many healthcare institutions are beginning to look at infection prevention as an all-encompassing department that requires specialization, training, and certified staff. Institutions create infrastructures that allow IPs to function broadly and develop facility-wide infection prevention practices. The infrastructure may include the addition of infection prevention educators, special coordinators of initiatives such as the programs that manage MRSA episodes, and data collection specialists, to name a few. Often the infrastructure requires IPs to interact intensively with medical staff, ancillary departments, hospital leadership, quality personnel, and safety and risk management departments. Leaders may give IPs authority and consultative roles to change organization-wide processes and practices.

The IP usually takes the lead to identify infection risk situations and prevention goals by developing a matrix that identifies the frequency and severity of each risk. From the matrix, the IP can prioritize initiatives to reduce or eliminate high-risk infections, the relative impact on the patient, and preventability

to ensure efforts focus on where changes can truly occur. In addition, the IP may choose the Healthcare Failure Mode Effect Analysis (HFMEA) to identify possible failure points and reengineer or redesign processes. The HFMEA may identify and allow the organization to eliminate areas of liability from adverse patient outcomes, such as hospital-associated infections, patient injury, and even death. Finally, the organization must include the IP's work and efforts in the overall strategic plan. The strategic plan should examine whether the facility has in place ample infection prevention resources, equipment, and personnel to achieve the "best practices" standard of care.

The strategic plan should include interventions to manage multidrug-resistant organisms, often referred to as MDROs or "superbugs," such as MRSA and vancomycin-resistant enterococci (VRE). IPs must educate employees about how to stop the spread of these organisms. Inservice training sessions include the following:

- Proper hand hygiene procedures
- Proper environmental cleaning practices
- Proper sterilization of equipment
- Use of disposable supplies
- Proper use and application of personal protective equipment
- Proper isolation techniques

## Preventing Infection

### PREVENTING CROSS-CONTAMINATION BY COMPLYING WITH HAND HYGIENE PROCEDURES

According to the medical literature, most hospital-associated pathogens are transmitted from patient to patient via the hands of healthcare personnel. Hand hygiene, therefore, is the simplest and most effective, proven method to reduce the incidence of HAIs. Despite this well-established relationship, compliance with hand hygiene among all types of healthcare personnel remains inconsistent. Identifying effective methods to improve the practice of hand hygiene can greatly enhance the care of patients and result in a significant decrease in HAIs.

Organizations should have detailed policies in place regarding when healthcare personnel must perform hand hygiene, for example, before and after applying gloves and when entering and exiting patient rooms. IPs should implement a mechanism of employee surveillance to ensure that healthcare staff members actually clean their hands when caring for patients. Other strategies that may facilitate hand hygiene and minimize cross-contamination include individual alcohol-based hand rub containers for each employee, strategically placed hand rub dispensers inside and outside of patient rooms, rewards for compliance with hand hygiene practices, and unit staff members appointed to act as role models and hand hygiene champions.

While the spread of infection to patients decreases with staff adherence to hand hygiene practices, staff may experience skin irritation as an adverse effect of the activity. Good skin integrity constitutes an important barrier to infection. Soaps and detergents can damage the skin when applied on a regular basis. Alcohol-based preparations are less irritating to the skin, and with the addition of emollients, staff may tolerate certain products better than others. Another potential barrier to hand hygiene compliance is the amount of time required to perform proper hand washing. Current recommendations for standard

hand washing suggest 15 to 30 seconds of vigorous friction with soap constitutes adequate hand hygiene. Given the many times during a nursing shift that hand hygiene should occur, nurses may argue that the time constraints impede their performance to accomplish other patient care duties. In fact, lack of time is one of the most common reasons cited for failure to wash hands. Because alcohol-based hand rubs require less time, organizations opt to purchase individual bottles of hand rub as a way to curtail the time concern.

## COST OF HAND HYGIENE INTERVENTIONS

Interventions designed to improve hand hygiene require organizations to invest significant financial and human resources. Costs develop as a result of educational/feedback initiatives, as well as for interventions that require equipment, such as more sinks, automated sinks, or new types of hand hygiene products. The costs incurred by such interventions must be balanced against the potential gain derived from reduced numbers of HAIs, potentially reduced lawsuits, and reduced staff and patient injuries.

## ORGANIZATIONAL BEST EFFORTS

According to healthcare literature, the best approach to improving hand hygiene compliance involves increasing frontline staff awareness. In addition, many organizations review the structural design of nursing units, pilot a number of new and innovative hand hygiene products, review workload to determine sufficient time to perform hand hygiene, and instill individual accountability to follow hand hygiene practices. When and if a lawsuit occurs because of an allegation of an HAI, all legal counsel in the litigation will request a timeline and description of the organization's best practice efforts to achieve staff commitment to hand hygiene.

## PREVENTING EXPOSURE TO CONTAGIOUS PERSONNEL

Healthcare organizations in most states conduct some type of health screening for infectious disease for their current employees and screen new employees at the time of hire. Medicare and Medicaid conditions of participation require that healthcare organizations establish and enforce a continuous process for inspection and report any hospital employee with an infection who may be in contact with patients, food, or laundry. The organization's failure to recognize obvious symptoms of an employee's poor health and to remove the employee from duty may create liability for the organization. As part of a facility's duty to provide quality patient care, processes should be in place to detect, reassign, and remove contagious staff from direct patient care.

## REDUCING THE RATE OF INFECTION IN THE HOSPITAL: POSTOPERATIVE INFECTIONS

According to conventional literature, experts agree that HAIs represent a worldwide health hazard and that HAIs are a major side effect of care and treatment, contributing greatly to morbidity, mortality, and the cost of care. Not surprisingly, many of the malpractice claims filed against surgeons involve surgical site infections. Many of the organisms that cause postoperative infection are normally present in healthy individuals. This premise is often used to counter plaintiffs' allegations of negligence in cases involving postoperative infections. For example, in *Roark v. St. Paul Fire and Marine Insurance Company*, a staphylococcal infection occurred in a patient's surgical wound site. Based on a review of the medical record and the institution's policies and procedures, the evidence established that physicians and staff followed standard procedures to establish the sterility of the supplies and instruments and that the environment met or exceeded national standards. An expert witness testified that most individuals who contract a staphylococcus infection after surgery have the same bacteria on their skin prior to surgery.



Because staphylococcus bacterium is found within the subcutaneous sweat glands and hair follicles of some patients, the organism may survive skin cleansing performed before surgery. A physician testified that susceptibility to staphylococcal infection varies from individual to individual and that there is no practical way to determine, prior to surgery, who may be more susceptible to staphylococcus infection or who may be a carrier of the bacteria. The expert witness concluded that staphylococcal infections are an unavoidable risk of surgery.

## INFECTIONS DUE TO MEDICAL EQUIPMENT AND DEVICES

Hospitals must ensure that staff follows proper procedures for cleaning, handling, storing, and sterilizing equipment and supplies. Thus, infections caused by contaminated instruments, equipment, or appliances may result in liability for the organization. Such cases often involve the use of improperly sterilized needles or unclean catheters. For example, in *Ernest Chester v. Mercy Catholic Medical Center of Southeastern Pennsylvania*, a patient developed a staphylococcal infection that caused cardiomegaly (an enlarged heart) and mitral valve prolapse. The patient claimed the infection was caused by improper catheter placement and failure to monitor the patient's condition, which resulted in contamination of the intravenous catheter entrance site. The patient also claimed that physicians did not properly diagnose the infection. The case ended with an undisclosed settlement to the patient.

In another case, *Rung v. St. Luke's Memorial Hospital Center*, a physician assistant used an unsterile needle to administer a tetanus shot to a patient. The patient claimed that the physician assistant's infant son touched the needle prior to the injection. The patient further claimed that she requested a different needle be used but that the physician assistant assured her there was no need to be concerned. The patient claimed that as a result of the contaminated needle, the medical staff was negligent in giving the injection, and she experienced a chronic infection resulting in permanent pain and loss of the use of her left arm. The jury ruled in the patient's favor, and the court awarded the patient \$1,889,700.

Another landmark case involving medical equipment and devices is *Brick v. Greenbriar Nursing Home*. An 83-year-old woman recuperating from colitis required a central venous catheter to administer nutrition. A nurse at the facility attempted to irrigate the catheter and in doing so noticed a break in the catheter. The nurse applied adhesive tape over the broken area. Subsequently, the patient developed a staphylococcus infection in her lungs and sustained neurological damage that affected her mobility and her ability to care for herself. The defendant nursing home claimed that the infection was a known risk of catheter use and that the infection may have occurred despite the break in the device. The parties settled before trial for the sum of \$450,000.

The reuse of disposable, single-use medical devices can be problematic. Some institutions reuse devices such as hemodialyzers, transducer domes, balloon-tipped catheters, cardiac catheters, catheter guide wires, biopsy needles, endotracheal tubes, anesthesia face masks, irrigating syringes, and manual resuscitators. TJC requires that a facility have in place written policies and procedures addressing the reuse of disposable items, and that these policies and procedures address the reprocessing of disposable items to be reused. When medical devices and equipment apparatus are explicitly labeled "for single use only," hospitals and physicians open themselves up to liability if they use the device more than once and the patient experiences a less-than-desirable clinical outcome. Guidelines and protocols regarding reusable products should be established, and the hospital should keep detailed records to substantiate that reuse does not jeopardize patient care.

## ANTIBIOTICS

The use or inappropriate use of antibiotic medication can become a legal issue in healthcare and result in litigation. Lawsuits alleging negligence on the part of the practitioner focus on:

- Failure to prescribe indicated antibiotics.
- Failure to adequately screen for sensitivity or properly monitor antibiotics use.
- Prescribing antibiotics that are clinically contraindicated.
- Inappropriate use of antibiotics for surgical prophylaxis.
- The subtherapeutic use of antibiotics.

In principal, it may be possible for a patient who develops an HAI caused by a resistant organism to recover damages resulting from the organism's resistance, if he or she can prove that the resistance was caused by the physician or hospital's indiscriminate use of antibiotics. In hospitals where antibiotic use is not left entirely to the discretion of individual physicians and where the hospital can take affirmative steps to control the use of antibiotics, legal exposure may extend to the hospital. Most hospitals now curtail liability and promote patient safety by using information technology that improves patient safety, such as computerized physician order entry systems and bar coding. These sophisticated systems provide physicians with choices for approved antimicrobial selection of medication, alert clinicians to allergic reactions, and provide for appropriate discontinuation of antibiotics according to national guidelines. Bar coding allows the clinician to scan a bracelet on the patient and a bar code on the medication validating that he or she administers the right medication to the right patient. Information technology helps to prevent adverse drug reactions, ensures timely medication administration, and prevents "near misses" as long as clinicians use the system as intended, without overriding or working around the safety alerts.

Standardization of systems also reduces liability for healthcare organizations. Institutions should review infection prevalence and current practice, look at best practice to improve performance, and provide staff with clear policies, procedures, and clinical guidelines to assure consistency in care. The infection prevention department may require that the medical staff, a medical staff committee, or hospital clinic teams regularly conduct a clinical review of policies governing antibiotic use. The work of the review may consist of:

- An assessment of clinical aspects of infections occurring in the facility.
- A review of pharmacy data determining antibiotic use.
- A pathogen resistance trend report from the hospital microbiology laboratory.
- Institutional observations, actions, and recommendations regarding antibiotic use.
- Restricting the use of a particular antibiotic if appropriate.

Institutions that proactively standardize policies for antibiotic use, track and trend antimicrobial data, and identify processes and practices for improvement will enhance the overall infection prevention program.

## PROTECTING HEALTHCARE PERSONNEL AND THIRD PARTIES FROM EXPOSURE TO INFECTIOUS DISEASES

The standards of the Occupational Safety and Health Act (OSHA) of 1970 ensure a safe and healthy work environment for employees. OSHA designed rules to minimize on-the-job risks for employees, including:

- Limiting exposure to toxic chemicals.
- Limiting exposure to infectious diseases.
- Limiting exposure to hazardous waste materials.

- Limiting exposure to hazardous equipment.

Healthcare institutions have a duty to protect the health of employees from exposure and injury. Healthcare personnel may be exposed to a wide array of health and safety hazards, including exposure to biologic agents, physical agents, stress, injury, and chemical agents. Under common law, employers must provide reasonably safe working conditions for their employees and must warn employees of unsafe conditions that they might not discover on their own. OSHA's general duty clause mandates each employer furnish to employees a place of employment that is free of recognized hazards that may cause, or are likely to cause, death or serious physical harm to the employee. Violations of this provision may result in heavy fines for the organization. In one provision of the law, OSHA possesses broad powers to investigate workplaces, review employer records, and conduct medical examinations to ensure that employees have a safe workplace.

In October 1993, OSHA issued an enforcement policy regarding occupational exposure to *Mycobacterium tuberculosis* (TB). The policy emphasizes that providers should:

- Implement control measures, including administrative and engineering controls and personal respiratory protection.
- Conduct risk assessments and develop a written TB control plan.
- Ensure early identification and management of individuals with TB.
- Provide purified protein derivative skin-testing programs.
- Develop educational programs for healthcare personnel.

## CONDUCT SURVEILLANCE OF PERSONNEL AND REVIEW IMMUNIZATION RECORDS

State laws addressing workers' compensation ordinarily cover an employee's lost time and medical care when the employee can prove he or she contracted the disease in the workplace. The employee may receive payment and compensation without proving fault or negligence on the part of the employer. In certain circumstances, employees who acquire work-related infections may be eligible for remuneration beyond what the workers' compensation system provides, if the employee can establish that the employer intentionally disregarded the risk of infection in the workplace. If an employee becomes infected with human immunodeficiency virus (HIV) in the course of employment, workers' compensation benefits may apply if the worker can demonstrate a causal connection between his or her HIV infection and employment. Specifically, the employee would need to prove that the incident occurred on the job involving a documented needlestick injury, puncture wound, or other exposure to HIV-contaminated blood or body fluids. Providers routinely conduct a health inventory on all new employees that includes immunization status and past health conditions that predispose the employee to certain communicable diseases. The health inventory guides an employer to determine whether an employee is at risk for disease.

Healthcare providers should monitor employees for the presence of infectious diseases or whether an employee is predisposed to or a carrier of infectious disease. Employers should make special efforts to monitor staff in high-risk areas, such as hemodialysis units. As pathogens such as HIV and Hepatitis C become prevalent in healthcare settings, healthcare providers should develop a comprehensive surveillance system for healthcare personnel in order to track and trend disease occurrences. Whether or not a provider knows that an employee has an infection, the organization should take steps to protect patients and other healthcare personnel from infection. Providers should rigorously monitor and enforce

compliance with CDC guidelines to reduce the risk of patients' exposure from healthcare personnel, including physicians.

In 1991, OSHA published regulations designed to reduce the risks of infection from bloodborne pathogens. This standard is the most pervasive regulation that OSHA imposed on healthcare organizations. The regulations apply to all occupational exposures from blood and other body fluids. Although most healthcare organizations comply with universal precautions, OSHA regulations mandate several additional guidelines:

- Develop an exposure control plan to eliminate or minimize exposure.
- Make Hepatitis B vaccine available to all employees at risk for exposure.
- Ensure that an employee exposed to an infectious agent receives testing to determine the presence of the organism and provide the employee with follow-up treatment and counseling.
- Implement certain engineering and work practice controls to eliminate or minimize job risks.
- Store and maintain sharps or contaminated materials in accordance with regulations.
- Communicate to employees and the public the nature of contaminated waste by affixing appropriate labels bearing biohazard symbols.
- Provide inservice training sessions for all employees at the time of initial employment and no less than annually thereafter.
- Maintain accurate and confidential records related to personnel training, vaccination, and management of exposures.

An example of the application of these standards occurred in 1994 at AmeriCare, a New Hartford, New York staffing agency. The agency received a citation for an alleged violation of OSHA's bloodborne pathogens standard. The firm received a \$44,000 fine for failing to offer Hepatitis B vaccinations to employees who had been exposed to blood and other infectious materials. In addition, AmeriCare failed to include all required information in its written exposure control plan.

## EMPLOYEE EXPOSURE AND TESTING

The social stigma associated with acquired immunodeficiency syndrome (AIDS) has added to the dilemma healthcare organizations face regarding workers accidentally exposed to a patient's blood and body fluids. Although workers' compensation laws may pay the medical expenses of testing and treatment, employees often try filing legal claims outside the workers' compensation system for negligent failure to disclose harmful conditions at the workplace, malicious intent to conceal harmful risks, or failure to use due care in keeping the workplace safe.

The CDC recommends that after a healthcare professional experiences a parenteral or mucous membrane exposure to blood or other body fluids, or has a cutaneous exposure involving large amounts of blood, the facility should inform the patient of the exposure and obtain the patient's consent to be tested for serologic evidence of HIV. If the patient is positive for HIV or refuses HIV antibody testing, the healthcare professional should be counseled and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. If the patient is seronegative, the healthcare professional should still receive a baseline HIV antibody test. The CDC recommends that no further follow-up of the exposed professional is necessary unless the patient is at high risk of HIV infection. Because of heightened employee concern, many hospitals have chosen to make serologic testing available to all personnel who fear they have been exposed/infected.



If the patient, after being informed of the incident, refuses HIV testing, the hospital's options depend on state law. Some states forbid testing without written informed consent. In Colorado and Florida, state law expressly allows testing, regardless of consent within certain guidelines. In at least two states (Florida and Maine), a court order may mandate patient testing.

## WHEN AN EMPLOYER DISCOVERS AN EMPLOYEE HAS AN INFECTION

Employers may need to determine what to do when they learn that an employee has an infection such as HIV. Employers often face a difficult dilemma deciding between facing charges of employee discrimination and facing repercussions that stem from an unknowledgeable public. Once a provider learns an employee has an infection, a representative should approach the employee confidentially and with sensitivity to determine the appropriate action to protect the employee, other healthcare personnel, and the patient population from transmission of infection.

The provider and employee should take reasonable protective measures that include limiting employee tasks to noninvasive procedures, ensuring that the employee wears double gloves at work, and ensuring that other elements of the exposure control plan are in place. When an employee does not agree with the procedures that the provider deems necessary, comments and actions of the provider and employee should be fully documented. After consideration of the accommodation efforts for the employee, balanced with consideration of patient safety, the employer may proceed with disciplinary action and/or employment termination if the employee refuses to comply with the exposure control plan.

## EMPLOYEE INSISTENCE REGARDING PRECAUTIONS

An employee may lawfully refuse to work in unsafe conditions and may also insist on wearing safety equipment on the job. OSHA does not permit employees to leave the job because of potentially unsafe working conditions. Rather, employees must inform their employer of the unsafe conditions or request an OSHA inspection of the workplace. If an employee is confronted with a condition presenting a real danger of serious injury or death, he or she may refuse in "good faith" to work until the employer removes the danger. To protect employees, the employer uses the reasonableness standard and removes hazards that (1) a reasonable person would believe presents a real danger of death or serious injury, and (2) causes danger of such an urgent nature.

When an employee insists on wearing more protective gear than the employer healthcare provider believes is necessary to prevent disease transmission, the employer must investigate the employee's rationale for wanting additional protective gear and educate employees regarding appropriate infection prevention techniques. If, after this process, the employee still insists on following procedures contrary to the recommended approach, legal advice should be sought regarding state law on the subject. Some state and federal statutes forbid discrimination against an employee for complaining about health hazards, even if there is no actual danger, as long as the employee has a reasonable belief that a danger exists.

Although the number of guidelines regarding patient care and employee health may seem overwhelming, it is important to realize that improvements in OSHA's guidelines have contributed to making the workplace safer, minimizing risks, ensuring proper infection prevention practices, eliminating employee discrimination, and improving the overall quality of healthcare.

## FEAR OF DISEASE CLAIMS

Increasingly, hospitals and physicians face claims for mental distress engendered by the mere possibility that a person may experience physical injury in the future. Examples of such allegations in the

healthcare context are fear of AIDS claims, which require particularly close analysis. In most states that allow fear of AIDS claims, the reasonableness of such claims depends not only on the existence of a physical injury, but also on whether the plaintiff was actually exposed to HIV. Some states, such as Florida and Tennessee, require the plaintiff to prove actual exposure to HIV, not the mere possibility of exposure, before they will allow recovery in fear of AIDS claims. Other states, such as Maryland and Virginia, do not require actual exposure but will allow recovery for the window of anxiety between the time the plaintiff learns of their possible exposure to HIV and the time he or she receives negative test results. In order to ensure that such claims are genuine, most jurisdictions still require certain minimum levels of proof, such as:

- Whether actual or only possible exposure occurred.
- Whether an emotional injury occurred.
- Whether the claimant will actually develop the feared condition.
- Whether a reasonable "window of anxiety" exists with which to mitigate damages.

## Ethical Issues

### OBLIGATION TO DISCLOSE TO PATIENTS THE PRESENCE OF A HEALTHCARE-ASSOCIATED INFECTION

In 2000, the Institute of Medicine released a report about the quality of healthcare titled *To Err Is Human: Building a Safer Health System*. This publication created public awareness about medical errors and the lack of safety in the nation's healthcare system. Thus, patients and family members requested to know more about what happens or happened during a stay in a healthcare facility. Research suggests that patients and the public support disclosure. The National Patient Safety Foundation urges healthcare professionals to disclose to patients errors and adverse events and be forthcoming about patient injuries and care complications when they occur. Ethical and professional guidelines recommend disclosure of medical errors and support informing patients about their care, treatment, and services.

Providers should inform patients when an HAI occurs. Courts have become increasingly insistent that physicians have a duty to fully disclose all pertinent facts concerning a patient's condition, even if the physician is convinced that he or she is acting in the patient's best interest by remaining silent. The informing obligation exists regardless of whether the condition is the result of negligence of the physician, a colleague, or the hospital. Failure to inform patients in such situations may result in liability for fraud, negligence, or conspiracy. Punitive as well as compensatory damages may be awarded in such situations.

### DUTIES TO NONPATIENTS

Providers' obligations to inform individuals of a communicable disease situation extend to persons other than patients. A duty of reasonable care extends to all employees, volunteers, and visitors on the premises. An individual who visits a hospital or medical facility during regular visiting hours and remains on the premises is an invitee to whom the hospital owes the duty of exercising ordinary care. If a third party develops an infection from a patient because of the provider's negligence, case law has established that damages may be awarded to the third party. Visitors of isolated patients, for example, should be warned of the risk of contracting the disease, and physicians and staff should document in the medical record that the visitor was so advised.

In the case of *Johnson v. West Virginia University Hospitals, Inc.*, a university police officer was called upon to help restrain a combative patient and subsequently received a human bite from the patient on his forearm. After the bite, the officer learned that hospital personnel knew the patient had AIDS. The officer sued the hospital for negligence, asserting that the hospital failed to advise him in advance that the patient had AIDS and that, as a result of the exposure to AIDS, he experienced emotional distress. The jury returned a verdict in the officer's favor for \$1.9 million.

In 1993, the Tennessee Supreme Court expanded the duty to protect third parties from exposure to communicable diseases through a ruling that imposed liability on a physician to warn a patient's family members of the risk of the patient's noncontagious disease. A couple whose son died of Rocky Mountain spotted fever sued the physician for negligence because the physician failed to warn the mother that she also was at risk of contracting the disease. The physician argued that since the mother was not his patient and Rocky Mountain spotted fever is not contagious from human to human, there was no duty to warn of the risk of exposure. The Supreme Court found that individuals who come in contact with the disease are at risk of carrying the disease and that the existence of the physician-patient relationship is sufficient to impose upon a physician an affirmative duty to warn identifiable third persons in a patient's immediate family against foreseeable risks emanating from a patient's illness. Clearly, the Tennessee Supreme Court's interpretation of the ruling suggests that physicians and healthcare personnel have a duty to protect the patient and the patient's family if they are at risk for contracting a disease. The premise that care is extended beyond the patient places the onus on healthcare professionals to thoroughly assess the patient's physical and social environment.

## INFORMED CONSENT

Informed consent means an agreement to do something or to allow something to happen, made with complete knowledge of all relevant facts, such as the risks involved or any available alternatives. For example, a patient may give informed consent to medical treatment only after the healthcare professional has disclosed to the best of his or her knowledge possible risks involved in accepting or rejecting the treatment. A healthcare provider or facility may be held responsible for an injury caused by an undisclosed risk. According to the American Medical Association (AMA), informed consent is more than simply getting a patient to sign a written consent form. Informed consent is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

In the communications process, physicians providing or performing the treatment and/or procedure should disclose and discuss with the patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure, including the risk of contracting an infection;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, the patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

The informed consent communications process or a variation thereof is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. Providing the patient relevant information has long been a physician's ethical obligation. The first case defining informed consent appeared in the late 1950s. Earlier consent cases were based in the tort of battery, under which liability was imposed for nonpermitted touching. Although battery claims occasionally occur when treatment is provided without consent, most consent cases generally center around whether the consent was "informed" (e.g., whether the patient was given sufficient information to make a decision regarding his or her body and healthcare). To avoid litigation, clinicians must know the importance of clear communication and how to document the communication process. Good documentation can serve as evidence that informed consent indeed took place. A timely and thorough documentation in the patient's chart by the physician providing the treatment and/or performing the procedure is evidence that the physician engaged the patient in an appropriate discussion. A well-designed, signed informed consent form may also be useful, but an overly broad or highly detailed form actually can work against the organization.

Forms that serve mainly to satisfy all legal requirements and contain broad language such as "all material risks have been explained to the patient" may not preclude a patient from asserting that actual disclosure did not include risks that the patient unfortunately discovered after treatment. At the other extreme, listing all of the risks may not be wise. A comprehensive listing of risks will be difficult for the patient to understand, and any omission from the list will likely be presumed undisclosed. To establish patients' awareness of hospital infections, some attorneys suggest that hospital admission consent forms include the risk of infection associated with any hospitalization and should state that the hospital cannot ensure that the patient will not contract an infection. Operative consent forms in many hospitals mention infection as a possible complication of surgical procedures.

## AN OBLIGATION TO PROVIDE CARE TO ALL

Patients with incurable infections may find access to healthcare services difficult. Historically, private hospitals did not have a legal obligation to accept nonemergency patients. However, in reaction to legal theories, statutes, and licensing agency regulations, the traditional rules governing a hospital's responsibility in this area have changed. Mandated in most states laws, hospitals must provide emergency care whenever requested. Denials of care to patients based on such factors as race or handicap are illegal. Any hospital that receives federal financial assistance has an obligation under Section 504 of the Federal Rehabilitation Act of 1973 to provide nondiscriminatory treatment. Thus, if the hospital staff member refuses to care for a patient with a contagious disease, the hospital has a responsibility to see that care is rendered, even if this means transferring the patient to another facility for patient care. Although there is generally no duty for a hospital to provide nonemergency services, failure to follow established hospital policy, such as hospital admission policies as related to race, sex, age, religion, or national origin, may result in liability under state and federal discrimination statutes.

Healthcare organizations must address personnel who refuse to care for patients with infectious diseases. The provider's personnel policies and procedures or employee handbook must describe administrative and human resource options or penalties if an employee refuses patient care. Employees should be reminded that the healthcare institution provides personal protective equipment, such as gowns, gloves, masks, and goggles, to protect them from transmission of infectious diseases. Healthcare institutions may attempt to accommodate an employee through reassignment, education, and counseling.

## ETHICAL ISSUES AND CONFIDENTIALITY



The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA or The Act). HIPAA standards address the use and disclosure of individuals' health information, called protected health information, by organizations subject to the Privacy Rule, called covered entities, as well as standards for individual's privacy rights to understand and control how his or her health information is used. Within HHS, the Office for Civil Rights (OCR) has responsibility for implementing and enforcing the Privacy Rule with respect to voluntary compliance activities and civil money penalties.

HIPAA assures that covered entities properly protect an individual's health information while allowing the flow of health information necessary to provide and promote high-quality healthcare. HIPAA strikes a balance between using information for care, treatment, and services, and protecting the privacy of people who seek medical care. Given that the healthcare marketplace is diverse, HIPAA is designed to be flexible and comprehensive to cover the variety of uses and disclosures.

Subtitle F of HIPAA addresses administrative simplification and encourages development of a health information system through established standards and requirements for the electronic transmission of certain health information. Organizations must implement policies and procedures to protect healthcare information and ensure compliance with HIPAA. IPs must ensure that proper disclosure of protected health information is done with diligence to protect patient confidentiality. IPs who report information for public disclosure should be aware that wrongfully disclosing individually identifiable health information violates HIPAA and could result in civil money fines against the organization. HIV antibody testing raises a number of legal issues. Healthcare providers are drawn into the debate about testing all hospitalized patients for HIV. The balancing of the rights of the infected and the rights of the uninfected to exercise self-protection is at the core of this issue. State laws differ on the treatment of this information, and many legislative proposals have been introduced at the state and federal level regarding confidentiality; thus, providers should remain current regarding evolving law in this area.

Discrimination against individuals who have AIDS or an HIV infection may occur because of the social stigma associated with the condition. Courts could hold a hospital liable for violating the Americans with Disabilities Act (ADA) if the hospital refuses to treat an individual with AIDS. For example, in *Glanz v. Vernick*, the hospital refused to perform a surgical procedure on a person diagnosed as HIV positive. The patient sued both the hospital and the physician who refused to operate, alleging that the medical team and institution discriminated against him on the basis of a handicap.

Physicians' obligation to treat HIV-infected patients should be addressed by institutional and medical staff policies. Some surgeons have publicly announced their refusal to operate on HIV-infected patients. Others physicians argue that patients should be treated based on their clinical condition. If such a patient is judged to be a candidate for cardiac surgery, for example, neither AIDS nor HIV infection should, in and of itself, prevent the surgery from occurring.

Although healthcare institutions cannot require physicians to accept AIDS or HIV patients in their private practices, the legal and ethical principles that require employees to provide care to AIDS and HIV patients applies to physicians who work in institutions. For example, a hospital's duty to treat emergency patients and to render appropriate care to admitted patients should have policies establishing the physician's obligation to treat all patients.

AIDS patients are entitled to competent medical care with compassion and respect for human dignity. A physician may not ethically refuse to treat a patient whose condition is within the physician's current realm of competence solely because the patient is seropositive. Medical ethics do not permit categorical discrimination against a patient based solely on his or her seropositivity. A person with AIDS needs

competent, compassionate treatment. A physician who is not able to provide the care and services required by an individual with AIDS should make an appropriate referral to physicians or facilities that are equipped to provide such services. Until the hospital and physician accomplish the transfer to another facility, the physician must care for the patient to the best of his or her ability.

In 1991, Dr. Nancy Rockmore Angoff published an article in the *Yale Journal of Biology and Medicine* titled "Do Physicians Have an Ethical Obligation to Care for Patients with AIDS?" Dr. Angoff suggests that before antibiotics, physicians took personal risks caring for patients. With the advent of AIDS, however, many healthcare personnel were not only unwilling to treat this incurable contagious disease because of fear of this deadly virus, but also because of the social stigma associated with the patients who contracted the virus (usually homosexuals and intravenous drug abusers). Dr. Angoff believes that each medical student, resident, and physician must come to terms with his or her feelings about caring for patients with this disease. The 40-page article examines in depth the ethical nature of an obligation to care for AIDS patients and concludes that a commitment to care for patients with AIDS does indeed exist. The practice of medicine itself and the physician-patient relationship are part of the physician's ethical responsibility to act always with concern for the well-being of the patient.<sup>1</sup>In 1997, the AMA's Council on Ethical and Judicial Affairs issued a statement that physicians have an obligation to treat AIDS- and HIV-infected patients. Looking broadly at the issue of a duty to care for patients, legal scholars and medical professionals consider ethics in any situation when physicians treat patients with infectious diseases, including polio, tuberculosis, MRSA, and VRE.

## INFECTION PREVENTION COMMITTEE REPORTS

According to TJC, hospital infection prevention and control programs should include a multidisciplinary committee that monitors infection rates, institutes prevention practices, and conducts surveillance of infections. Plaintiffs' attorneys may become interested in the proceedings, records, and reports of these committees. Accordingly, protection of patients' confidentiality, names of personnel involved in hospital infection surveillance, and the infection prevention reports themselves have become controversial issues in terms of the discovery of these reports. Courts have sought to balance the desire of infection prevention personnel to maintain confidentiality with plaintiffs' need for information to support their allegations. In response to court decisions that have found infection prevention and control program records discoverable, the majority of states have enacted statutes to protect such records.

The New Hampshire Supreme Court ruled that the defendant hospital's infection prevention committee minutes and epidemiologist's report were privileged and not subject to disclosure in an action brought by a patient diagnosed with herpes after giving birth at the hospital. The concerns of the patient's husband led the hospital nurse epidemiologist to conduct an investigation and report to the infection prevention committee whether the patient could have contracted the infection while in the hospital. State statutes indicate records created to evaluate patient care for quality assurance purposes are privileged. The trial court found that the privilege applied only to committee records related to quality assurance and since the hospital had separate quality assurance and infection prevention committees, the records were not privileged. However, the Supreme Court found the infection prevention committee met a definition of a quality assurance committee and that the reports were privileged because the infection prevention committee served a quality assurance function when it investigated the source of the plaintiff's infection.

## RISK MANAGEMENT

Risk management functions encompass activities that are intended to conserve financial resources from loss. TJC mandates that hospitals have a safety and risk management program in place to provide a physical environment free of hazards and to manage staff activities to reduce the risk of human injury. A

risk management program must involve a risk assessment of the buildings, grounds, equipment, occupants, and internal systems plus policies and procedures for the timely reporting and resolution of situations that pose an immediate threat to life, health, or property. An effective risk management program includes the following components of risk identification, risk analysis, risk control, and risk financing.

- Reducing financial losses through effective investigation and management of claims.
- Developing a patient representative program.
- Reviewing and coordinating insurance programs.
- Inspecting the premises and discovering deficiencies in the physical plant.
- Reviewing policies and procedures to reflect acceptable quality of care.
- Investigating adverse incidents and reviewing incident reports.
- Reviewing patient grievances.
- Conducting educational programs to minimize future risks.
- Conducting root cause analysis to determine what contributes to an adverse event.

The risk manager must work closely with the IP to identify, monitor, and control HAIs. A facility should adopt a team approach to control the spread of disease and prevent further outbreaks. Both risk management and the IP can handle matters such as noncompliance with infection prevention procedures, breaks in sterile technique, or equipment contamination. The infection preventionist should inform the risk manager of incidents such as:

- Preventable infections
- HAIs
- Infections that could lead to a malpractice claim
- Infections that contribute to the death of a patient

In addition, risk management and infection prevention should collaborate to identify high-risk patients, such as neonates, the elderly, patients in burn units or the ICU, or patients undergoing a specific procedure who appear at risk for infection. IPs should institute a surveillance and screening program to monitor patient outcomes and should consider the following:

- Whether risk factors exist before surgery.
- Whether early identification of infected patients reduces further infection or cross-infection.
- Whether isolation or barrier protection prevents cross-infections.
- Whether patient care areas have adequate infection prevention devices and supplies.
- Whether the institution empties infectious waste containers in a timely manner in accordance with the hospital's hazardous materials and waste program.
- Whether the organization has effective cleaning products or techniques, equipment, and supplies for sterilization, disinfection, and decontamination purposes.
- Whether written policies and procedures address reusable and disposable items and the shelf life of all stored sterile items.
- Whether written policies and procedures address the appropriate handling of soiled and clean linen.
- Whether written guidelines address infection prevention in anesthesia, surgery, and post-anesthesia care areas.

- Whether infection prevention education exists for healthcare personnel at the time of orientation and at least annually.
- Whether staff complies with organizational policies and procedures.

Collaboratively, the IP and risk management department should develop policies and procedures to identify infection risk and limit the spread of infectious diseases among personnel. Periodically, risk management should review OSHA regulations pertaining to bloodborne pathogen exposures and communicate to the infection preventionist changes in regulation.

## RECENT REGULATORY CHANGES AND FUTURE IMPACTS

On August 22, 2008, CMS published in the *Federal Register* its final rule on the 2008 Medicare hospital inpatient prospective payment system (IPPS). The CMS rule says that IPPS payment reforms restructure the inpatient diagnosis-related groups (DRGs) to account more fully for the severity of each patient's condition. In addition, the rule includes important provisions to ensure that Medicare no longer pays for the additional costs of certain preventable conditions, including infections acquired in the hospital. Other provisions of the rule explain:

- Payments to all hospitals will increase by an estimated average of 3.5 percent for fiscal year 2008, when all provisions of the rule are taken into account, primarily as a result of the 3.3 percent market basket increase.
- Payments will increase for hospitals serving more severely ill patients and decrease for those serving patients who are less severely ill.
- New methodologies will calculate outlier payments and capital cost reimbursement, which are intended to be more accurate.
- No payment to organizations for never events means a provision of the Deficit Reduction Act of 2005 will prevent Medicare from giving hospitals higher payments for the additional costs of treating a patient who acquires a condition (including an infection) during a hospital stay.
- The Deficit Reduction Act requires hospitals to begin reporting secondary diagnoses that are present on a patient's admission. Beginning in 2009, hospitals will not receive payment at a higher rate unless the hospital determines that a patient has a condition present on admission.
- New reportable quality measures in 2008 qualify hospitals for the full market basket update in fiscal year 2009. Failure to report certain measures will result in a 2 percent penalty.
- CMS will measure 30-day mortality for Medicare patients with pneumonia and will develop reportable measures of surgical care.

The effect of federal regulations causes transparency about where and when a patient develops a condition and possibly how and what caused the condition. With transparency also comes the possibility that patients or family members will hold medical institutions accountable for healthcare outcomes.

## Conclusions

Healthcare providers and facilities owe a legal duty of care to their patients. Healthcare providers must exercise that degree of care and skill that could reasonably be expected of a normal, prudent practitioner, and they also have an ethical obligation to act in the patient's best interests. Similarly, healthcare facilities have an obligation to provide a safe environment to protect patients from harm in the course of receiving care. They have a duty not only to establish necessary systems and protocols to

promote patient safety, but also to take reasonable steps to ensure that the healthcare staff complies with systems, protocols, policies, and procedures.

In the context of HAIs, what constitutes reasonable practices and protocols may be a moving target during an outbreak, particularly as infection prevention measures are revised to reflect new evidence about disease virulence, transmission routes, and key control methods. The area of infection prevention is one dominated by guidelines and directives, and failure to comply with recommended practices will be one factor that may indicate a failure to meet an appropriate standard of care. In many areas of practice, courts often look to guidelines or standards of practice to help determine the legal standard of care. Summarizing lawsuits that have stemmed from alleged lapses in infection prevention practices help IPs identify legal duties that healthcare providers and facilities owe to patients to ensure their safety.

If a patient has been harmed or exposed to risk of harm, providers have a duty to disclose that information to the patient or family. When errors have occurred, or when some risk of harm exists, state, federal, and local laws guide disclosure of patient identifiable health information to regulatory authorities, accrediting bodies, or other government agencies.

The information in this chapter does not constitute legal advice. IPs and healthcare organizations should consult with legal counsel regarding specific infection prevention questions or concerns.

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## Staffing

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## Abstract

*The role of infection preventionists has expanded as a result of the emergence of new diseases; changes in the healthcare delivery system, including use of new technologies and changes in reimbursement policies; social and political factors, such as the shortage of nurses; mandatory reporting of healthcare-associated infections; the need for emergency preparedness plans; and an increased focus on patient safety. The functions of an infection preventionist now include identification of infectious diseases; surveillance and epidemiological investigation; prevention and control of the transmission of disease; and program management, communication, research, and education. Infection preventionists also use their epidemiological skills to monitor and prevent noninfectious adverse outcomes related to patient safety. Recommended staffing levels may be outdated, necessitating the need for research on the appropriate staffing levels for infection prevention and control programs in the changing healthcare system. As the U.S. healthcare system continues to evolve, infection preventionists have an opportunity to participate in and lead interdisciplinary teams aimed at improving safety and quality of patient care efficiently by implementing evidence-based clinical practices.*

## Key Concepts

- Healthcare delivery is changing, and the infection preventionist role is expanding.



- Existing recommendations regarding appropriate staffing levels for infection prevention and control programs are outdated or incomplete.
- Levels of bedside nurse staffing have been associated with patients' risk for healthcare-associated infections.
- Reduction of healthcare-associated infections has global interest, but the staffing issues are different for developed and developing countries.
- Healthcare information technology will likely affect infection preventionist workflow and staffing.

## Background

In the past 20 years, the overall incidence of healthcare-associated infections (HAIs) has increased 36 percent.<sup>1</sup> Annually, in the United States, there are nearly 2 million patients stricken with HAIs, which translate to more than 5 percent of all hospitalized patients. Most of these infections are associated with the presence of an invasive device (e.g., a vascular access line, ventilator, or indwelling urinary catheter) or surgical procedure.<sup>2</sup> More than 70 percent of the bacteria that cause these infections are resistant to at least one of the drugs most commonly used to treat them. Nearly 100,000 of the patients with HAIs are estimated to die.<sup>3</sup> These estimates rank HAIs as the sixth leading cause of death in the United States.<sup>4,5</sup>

In 1992, the Centers for Disease Control and Prevention (CDC) estimated the total hospital-related financial burden of HAIs to exceed \$4.5 billion.<sup>3</sup> Using the Consumer Price Inflator, this converts to more than \$7.5 billion in 2013 dollars. However, the original cost estimate was based on infection rates measured in the Study on the Efficacy of Nosocomial Infection Control (SENIC), which was conducted in the mid-1970s.<sup>6</sup> More recently, researchers have used matched case-control studies to estimate increased length of stay and hospital costs of HAIs in specific settings.<sup>3,7,8</sup> HAIs caused by drug-resistant pathogens have increased costs, morbidity, and mortality.<sup>9,10</sup> Based on the more recent studies, and taking into account the increased number of HAIs caused by drug-resistant pathogens, the CDC now estimates the annual healthcare cost of HAIs to be up to \$33 billion a year.<sup>11</sup>

The high morbidity, mortality, and costs associated with HAIs are unacceptable because a large proportion of HAIs are preventable. For example, 66 intensive care units (ICUs) in southwestern Pennsylvania formed a coalition with the goal of decreasing HAI rates.<sup>12</sup> Using a multifaceted approach, these ICUs obtained a 68 percent decrease in central line–associated bloodstream infection rates over a 5-year period. A similar reduction was also found in 103 ICUs in Michigan.<sup>13</sup> In both of these projects, important components of the multifaceted approach included implementation of evidence-based guidelines, accurate measurement of the infections, and feedback to clinicians, as well as changing the organizational culture to promote patient safety.<sup>14</sup>

The Institute for Healthcare Improvement's national initiative to protect patients from 5 million incidents of medical harm during a span of 2 years includes specific interventions aimed at preventing surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonias, and methicillin-resistant *Staphylococcus aureus* (MRSA) infections.<sup>15</sup> These infection-related performance

improvement initiatives certainly include the infection preventionist (IP). Often, the IP is also involved in other similar quality improvement projects that are not infection related.

As a result of the morbidity and mortality associated with HAIs and the knowledge that many are preventable, American consumer groups (e.g., the Committee to Reduce Infection Deaths and the Consumers Union) have called for mandatory public reporting of individual hospital infection rates in an effort to raise public awareness and motivate hospitals to make infection prevention a top priority. Additionally, because of the magnitude of the HAI and antibiotic resistance problem in hospitals, and the increasing demand for healthcare information, many states now mandate or induce hospitals to publicly disclose data about their performance and outcomes in relation to these infections.

Furthermore, with the growth in healthcare spending spiraling upward and surpassing \$2 trillion in 2006, President Bush signed the Deficit Reduction Act, which required the secretary of the Department of Health and Human Services to identify hospital-associated conditions (HACs) that are: (a) high cost or high volume or both, (b) result in the assignment of a case to a diagnosis-related group (DRG) that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. For hospital discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case would be paid as though the secondary diagnosis was not present and Medicare prohibits the hospital from billing the beneficiary for the difference between the lower and higher payment rates. Rather, the hospital is being encouraged to prevent an adverse event and improve the quality of care it is giving to Medicare patients. In the first year, 10 HACs were identified, three of which were infections (i.e., catheter-associated urinary tract infections [CAUTIs], vascular catheter-associated infections [VCAIs], and selected surgical site infections [SSIs]). Additionally, the following infections are being considered for the future: ventilator-associated events, *S. aureus* bloodstream infections, *Clostridium difficile* infections, and methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

In addition to the changes associated with mandatory reporting of infections, infection prevention activities have increased with the advent of new diseases such as acquired immune deficiency syndrome (AIDS), sudden acute respiratory syndrome (SARS), and avian influenza; the emergence of resistant strains of old diseases such as multidrug-resistant pulmonary tuberculosis; and the need for emergency preparedness.<sup>16</sup> For example, the increased number of infections caused by multidrug-resistant organisms has increased IPs' activity related to monitoring, safe patient placement, and assessing existing patient care practices.<sup>17</sup> IPs are also instrumental in ensuring that their facilities are in compliance with applicable local, state, and federal regulations, including various Occupational Safety and Health Administration (OSHA) requirements.<sup>18</sup>

Other important healthcare delivery changes affecting the IP role relate to how less seriously ill patients increasingly receive care and services in home, community, or outpatient settings, leaving hospitals with a majority of "sicker" or higher acuity patients. The result is greater diversity in patient population and more variation in the location in which complex, invasive procedures are performed (e.g., home care, clinics, outpatient surgery centers) and an increasing need for IPs in these settings. These changes also increase the challenge of performing an essential infection prevention task in the acute care setting: surveillance. To develop an effective surveillance system, acute-care IPs need to incorporate the data limitations caused by short patient stays and patient populations with dissimilar risk factors. For example, developing surveillance systems and interpreting results from extended care or ambulatory care agencies are difficult because these patient populations may have diverse risk factors. In addition,

there is often an absence of diagnostic tests to aid in decision-making. Access to medical records from multiple care settings can be more labor intensive for the IP, and denominators may be difficult to establish.

These changes in the organization and delivery of services have expanded the role of many IPs and expanded their required depth of knowledge. In acute care or long-term care facilities, IPs now increasingly operate outside of more traditional infection prevention and control programs. They may have responsibility for combinations of acute and nonacute healthcare facilities, such as freestanding surgery units, medical and dental clinics, child and adult day care centers, dialysis centers, rehabilitation services, and others. IPs may provide consultation on prevention and control measures for new diagnostic or therapeutic procedures in a variety of new care settings.<sup>19</sup> With increasingly complex technical procedures being performed in a variety of nonacute care settings, there is the potential for substandard sterilization and disinfection procedures when workers with limited experience and training perform these procedures in decentralized locations. In addition, healthcare administrators are now more likely to view the infection prevention and control program as part of a larger system for monitoring, preventing, and controlling adverse outcomes. Therefore, the duties of IPs in large healthcare systems may include not only infection prevention and control program activities for a single facility but also system-wide responsibilities for specific functions (e.g., construction, education, program management).

In summary, the context of healthcare has changed due to many factors. As a result, the role and responsibilities of IPs are changing and expanding. Performance improvement is being promoted by providing performance feedback and tools to monitor processes, sharing lessons learned and best practices. The IP has a natural role in these activities; however, with the increased responsibilities and limited resources of many infection prevention departments, meeting these new roles may be challenging.

## Basic Principles

### EVIDENCE AND RECOMMENDATIONS FOR STAFFING OF INFECTION PREVENTION DEPARTMENTS IN ACUTE CARE SETTINGS

In 1985, the CDC published the SENIC study.<sup>20</sup> SENIC provided estimates of the magnitude of HAIs and quantified the effects of implementing specific elements of infection prevention and control programs on lowering infection rates. The SENIC findings showed a reduction in HAIs with the presence of one IP for every 250 hospital beds and the participation of a physician knowledgeable about infection prevention. However, with the changes in the healthcare system, this recommendation is very dated.

In the 1990s, participation in the CDC's National Nosocomial Infections Surveillance System (NNIS) required one IP full-time equivalent (FTE) for the first 100 beds and then one FTE for each additional 250 beds.<sup>21</sup> Currently, the CDC's National Healthcare Safety Network (NHSN) requires a trained infection control professional or hospital epidemiologist to be in charge of the program. In addition, NHSN requires that data reporters complete online training courses related to the methods and definitions used in the surveillance protocols. Training materials and information about enrollment in NHSN can be accessed on the CDC Website at: <http://www.cdc.gov/nhsn/enrollment/index.html>.

Public health codes of individual states often regulate the actual staffing of infection prevention and control departments. However, these regulations are often vague. For example, Connecticut's Public Health Code 19-13-D3 states that in short-term hospitals,

There shall be an individual employed by the hospital qualified by education or experience in infection prevention, surveillance, and control who shall conduct these aspects of the program as directed by the hospital infection control committee. This individual shall be directly responsible to, and be a member of, the infection control committee. This individual shall make a monthly report to this committee. The time allotted to this position shall be in accordance with current national and professional standards. <sup>22</sup>

The Joint Commission lists standards for infection prevention and control, which include minimizing the risk for development of an HAI through an organization-wide infection prevention and control program, identification of risk for the acquisition and transmission of infectious agents on an ongoing basis, effective management of the infection prevention and control program, collaboration of representatives from relevant components and functions within the organization in the implementation of the program, and allocation of adequate resources to the infection prevention and control programs. <sup>23</sup> However, there is no specific staffing requirement.

The role of the IP and issues related to infection prevention staffing have been addressed in both descriptive and proscriptive publications. <sup>24,25,26,27,28</sup> For acute care settings, participants in the Delphi study <sup>19</sup> recommended a median of one IP for every 100 occupied beds in a 100-bed acute care setting. The ratio decreased slightly as the size of the facilities increased (e.g., to more than 500 beds) (Table 9-1). The recommendations from the Delphi study were consistent with the findings from the CDC's NNIS study, in which the median reported staffing is one IP for hospitals with an average daily census of 115 patients.<sup>21</sup>

Several state and national surveys have been conducted in recent years to ascertain the staffing levels and resources available to infection prevention and control departments. As part of the Prevention of Nosocomial Infections and Cost Effectiveness (PNICE) study, researchers surveyed NHSN hospitals in 2007 and 2011 to describe the state of infection prevention and control departments around the country. <sup>29,30</sup> The 2007 survey of 289 hospitals found that the median staffing was one IP per 167 beds, <sup>29</sup> and these results were similar to those found in two other state surveys conducted at the same time. <sup>31,32</sup> For example, in Massachusetts hospitals, the average number of beds per IP was 178, with a median of 166.<sup>31</sup>

Encouragingly, the 2011 follow-up PNICE survey of almost 1,000 NHSN hospitals found higher staffing levels with an average number of 1.2 FTE IPs per 100 beds (standard deviation = 1.2). <sup>30</sup> A study conducted by Krein and colleagues also showed a statistically significant increase in staffing ratios from 0.67 to 0.80 FTE IPs per 100 beds in nonfederal hospitals between 2005 and 2009, and a similar increase in Veterans Affairs hospitals in the same time period (0.70 to 0.88 FTE IPs per 100 beds).<sup>33</sup>

**Table 9-1** Recommendations From a Delphi Study for Infection Preventionist Staffing by Occupied Beds

Full-time Equivalent	Facility Size	Acute Care	Setting Multisetting	Long-term Care
Median	100	1.0	1.0	0.8
	200	1.6	1.8	1.1
	300	2.5	2.5	2.0

	400	3.4	3.0	2.5
	500	4.0	3.5	3.0
	> 500	4.0	3.5	3.0
Range	100	1.0	0.3	0.5
	200	1.0	1.0	1.2
	300	1.5	1.7	2.0
	400	3.0	3.5	2.7
	500	3.5	3.5	3.0
	> 500	5.5	5.5	4.5

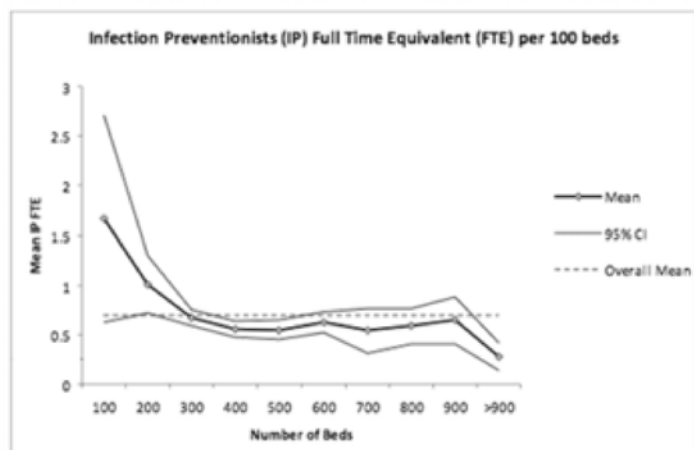
From O'Boyle C, Jackson M, Henly SJ. Staffing requirements for infection control programs in US health care facilities: Delphi project. *Am J Infect Control* 2002;30:321–333.

The PNICE researchers also found IP staffing ratio in hospitals was significantly negative related to bed size with smaller hospitals having higher staffing ( $p < .001$ ) (Figure 9-1).<sup>29</sup> The negative correlation between IP staffing and hospital size seen in this study suggests potential economies of scale, which means that in larger hospitals one IP is able to provide more services. Although the researchers were not able to test directly for economies of scale, the variation of staffing across hospital size clearly illustrates the inappropriateness of assuming that a single minimum IP staffing ratio would be adequate across a variety of settings. In the late 1990s, publications from professional organizations for IPs, including the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), recommended that factors other than bed size be used as criteria for determining IP staffing resources. These factors include the complexity of care within the healthcare system, the diversity of patient population, and the scope of the infection prevention and control program.<sup>34,35</sup> Similarly, an expert panel on HAI prevention convened by the state of Massachusetts also recommended that staffing levels take into account the complexity of the patient population and the range of clinical services provided.<sup>36</sup> The panel recommended staffing of 1.0 to 1.5 FTE IPs per 100 occupied beds, with institutions with more complex mix of cases and clinical services maintaining staffing at the higher end of the range.

**Figure 9-1.**

Results from the Prevention of Nosocomial Infections and Cost Effectiveness (PNICE) study. (From Stone P, Dick A, Pogorzelska M, et al. Staffing and structure of infection prevention and control programs. *Am J Infect Control* 2009;37(5):351-357.) [View Image](#)

The current research examining the impact of IP staffing in infection prevention and control departments and availability of physicians in the prevention of HAI is sparse. In a systematic review of research examining staffing and HAI,





42 articles were audited. <sup>37</sup> In this review, the researchers found that three investigative teams examined the level of infection prevention staffing and patients' risk for HAI, <sup>38,39,40</sup> two of which found higher levels of infection prevention professional staffing were significantly related to lower HAI rates. <sup>39, 40</sup>

Every few years the Certification Board of Infection Control (CBIC)<sup>24,41</sup> conducts a task analysis to identify the activities, skills, and knowledge necessary for IPs to fill their current role. In the most recent analysis, CBIC found that the IP role consists of infectious disease processes, performing surveillance and epidemiological investigations, initiating interventions to control and prevent transmission of infectious agents, managing the infection prevention and control program, participating in research, educating healthcare personnel (HCP), and communicating to HCP and communities about infection prevention measures.

In the PNICE survey described previously, the investigators found that IPs in acute care settings spent the largest proportion of their time collecting and analyzing data related to infections (Table 9-2). <sup>29</sup> This is similar to the results from an expert Delphi panel, from which it was estimated that 39 percent of IPs' time was spent on surveillance and identifying infections, <sup>19</sup> and a recent survey of New York IPs, who reported spending 45 percent of their time on surveillance. <sup>32</sup> Although accurate and consistent case-finding is important in reducing infections, actively working to change the organizational culture has also been found to be an important part of the multifaceted approach needed to promote patient safety and reduce infections.<sup>12,14</sup> It is possible that this aspect of the roles was not captured in the survey.

Additionally, it may be possible that IPs are not yet participating in this essential activity. In the most recent practice analysis published by CBIC, a new activity category entitled "management and communication" has been identified. <sup>42</sup> Although it is not clear if this category fully captures the new roles and responsibilities, we encourage researchers in the future to assess IPs' leadership and involvement in teamwork and quality improvement activities aimed at the establishment of evidence-based clinical practices.

**Table 9-2** Activities Reported by Infection Preventionists Regarding How They Spent Their Time (

Activity	Percent of Time		
	Median	Mean	SD
Collecting, analyzing, and interpreting data on the occurrence of infections	49.0	44.5	14.3
Policy development and meetings	14.0	15.0	8.8
Daily isolation issues	10.0	12.9	9.0
Teaching infection prevention and control policies and procedures	10.0	13.0	6.2
Other (e.g., product evaluation, employee health, and emergency preparedness)	5.0	8.8	8.2
Activities related to outbreaks	5.0	6.1	4.8

Means are the average percent of time reported by all respondents. Means do not sum to 100 percent due to rounding.

Adapted from Stone P, Dick A, Pogorzelska M, et al. Staffing and structure of infection prevention and control programs. *Am J Infect Control* 2009;37(5):351-357.

The PNICE survey also provided information on the experience and certification of the IPs working in these hospital infection prevention and control programs.<sup>29</sup> The researchers found that 47 percent of the participating IPs were certified and 24 percent had less than 2 years of experience. This has important implications for infection prevention and suggests that reaching out to new IPs to provide education and role transition should be a priority. The certification process may also be important for these new IPs because the certification examination is designed to measure minimum competence for practice. In addition, recent studies have suggested a potential association between certification in infection control and patient outcomes.<sup>43,44</sup> In a recent study of California hospitals, researchers have found that having a certified infection control director was a significant independent predictor of lower multidrug-resistant organism HAI rates.<sup>43</sup> Furthermore, Krein and colleagues have found an association between the presence of a certified IP and the use of policies aimed at reducing central line-associated bloodstream infections.<sup>44</sup>

## INFECTION CONTROL STAFFING IN NONACUTE CARE SETTINGS

The delivery of healthcare in the United States has changed dramatically over the last few decades with an increase in services provided in nonacute settings such as skilled nursing facilities and ambulatory clinics.<sup>45</sup> To reduce the incidence of infections in nursing homes (NHs), it was mandated by the 1987 Omnibus Reconciliation Act that each NH have an individualized infection prevention and control program, and it was recommended that NHs with 250 to 300 beds need a full-time IP.<sup>46</sup> It was also recommended that the IP have specific qualifications and training in epidemiology and infection control. While the presence of an IP to lead the infection prevention and control program is not mandated in NHs, the role is increasingly more common. For example, in Maryland in 2003, 8.1 percent of the NHs reported employing an IP; and there was a fivefold increase to 44 percent in 2008.<sup>47</sup> Similarly, in a survey of Michigan NHs, it was found that 50 percent had a full-time IP.<sup>48</sup> However, NH IPs are less likely to receive additional formal training in infection prevention and control (i.e., 8 percent compared to 95 percent of acute care IPs) and are more likely to have additional noninfection-related responsibilities.<sup>49</sup> Better understanding of the optimal role and training of the IP in NHs is needed.

While there are similarities between acute care and long-term care settings in the structures and processes needed to implement effective infection control (e.g., trained and/or certified IPs, accurate measurement of HAIs and processes, feedback and positive organizational climates), there are also important differences that impact infection control staffing and the way that infection prevention and control are conducted in these settings.<sup>50</sup>

Ambulatory care centers are another setting where infection control infrastructure and resources are often lacking.<sup>51</sup> In 2010, the CDC published a guide to infection prevention in ambulatory care outlining the minimum expectations for safe care.<sup>52</sup> The key recommendations outlined for infection control in this setting are to:

1. Develop and maintain infection prevention and occupational health programs.
2. Ensure sufficient and appropriate supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, personal protective equipment, injection equipment).



3. Ensure at least one individual with training in infection prevention is employed by or regularly available to the facility.
4. Develop written infection prevention policies and procedures appropriate for the services provided by the facility and based upon evidence-based guidelines, regulations, or standards. 52

## HOSPITAL EPIDEMIOLOGIST STAFFING AND HEALTHCARE-ASSOCIATED INFECTIONS

A 2006 survey of Society for Healthcare Epidemiology of America (SHEA) members reported on the expanding roles of healthcare epidemiology and infection control and found varying staffing levels in hospital epidemiology and infection control departments with a mean number of physician FTE of 0.85 for the smallest institutions to 1.79 FTEs for hospitals with more than 600 beds. 53 Of the members who responded to the survey, the vast majority (91 percent) provided hospital epidemiology services, but only 65 percent were specifically compensated for these services. A survey of California hospitals found that less than half of the hospitals reported the presence of any physician hospital epidemiologist (HE) with less than 4 percent of hospitals reporting the presence of a full-time HE. These findings were also seen in the 2011 PNICE survey that demonstrated a lack of HE in almost 50 percent of the hospitals. 30

These data suggest that in many cases resources for hospital epidemiology are below those recommended in peer-reviewed literature.

## NURSE STAFFING AND HEALTHCARE-ASSOCIATED INFECTIONS

Nurses are the largest workforce in hospitals, and although the number of nurses has grown in the last few years, a shortage still exists in many areas and is predicted to become worse in the coming years. 54 Also, staff nurses have the most direct and continuous role in performing the procedures and interventions on which the risk for infection often hinges, making them a critical component of infection prevention.

In the last 10 years, there has been much interest in gaining an understanding of the relationship between nurse staffing and patient safety outcomes such as HAIs. To examine these issues, research projects have been funded by the Agency for Healthcare Research and Quality, the National Institutes of Health, and the Robert Wood Johnson Foundation, as well as other agencies. A working group meeting of expert consultants organized in 2001 by the Division of Healthcare Quality Promotion and the CDC discussed available research on nurse staffing and HAIs and provided input to the CDC, nursing leadership, and other stakeholders on strategies for dealing with the problem of nurse staffing. 55,56

They concluded that there is a growing evidence base examining the relationships between nurses' working conditions in general (with staffing included as an important aspect of working conditions) and patient safety outcomes such as HAIs. In an effort to bring further clarity and synthesize this evidence, reports have been conducted, 57,58,59 including a recently published comprehensive review specific to HAIs.37

In a comprehensive review of original studies published since 1990, 39 publications were identified in which the relationship between nurse staffing and HAIs in the hospital setting was examined. 37 Although the limitations in the study designs prevents the determination of a specific evidence-based nurse staffing level benchmark that is associated with decreased risk for HAI, trends are apparent from this research. For example, although only two investigators studied ventilator-associated pneumonia (VAP) 60

,<sup>61</sup>, both reported that patients being cared for in an ICU with lower levels of nurse staffing had increased risk for VAP. The exact mechanism for this association was not studied. Although it is possible that when staffing is short, the nurses are unable to provide recommended care such as keeping the patient's head of bed elevated. <sup>62</sup> Burnout is another potential explanation for the association seen between patient-to-nurse ratios and urinary tract and surgical site infections as reported by a recent study conducted by Cimiotti and colleagues. <sup>63</sup> Furthermore, researchers studying organism-specific HAI using single-site designs all found the level and/or the use of nonpermanent staff significantly related to a patient's infection risk. The notion that being cared for by float nurses versus full-time permanent staff nurses in ICUs could put a patient at risk for HAI may seem surprising. However, it is in keeping with Pronovost's description of ICU work environments and how important it is to have good communication channels with strong interdisciplinary teamwork. <sup>64</sup> Temporary staff may lack specific training and familiarity with institutional procedures and "best practices" for preventing HAIs. Hospital administrators, nurse managers, and IPs should be aware of the importance of interdisciplinary teamwork and the need for both consistent training and adequate nurse staffing in reducing HAIs.

## SUMMARY

In summary, the existing recommendations regarding appropriate staffing levels for infection prevention and control programs are outdated or incomplete. Many recommendations were made before the reorganization of healthcare delivery and the new functional demands on IPs. The critical staffing challenge for IPs is to identify those activities that are essential to the infection prevention and control program and to quantify the time and resources necessary to accomplish those activities. More research is needed to address methods by which IPs can fully integrate their expanded responsibilities (i.e., across the healthcare continuum) into meaningful cost-effective infection prevention and control programs. Periodic assessments of the needs, resources, and strengths of the infection prevention and control program can help clarify the program's goals and activities and help it better reflect the mission of the larger healthcare organization.

## Future Trends

Healthcare information technology is expanding in all sectors. Information and informatics infrastructure are critical to the IP role. There is considerable promise related to electronic healthcare records and improving adherence to guidelines and improving the workflow of IPs through electronic surveillance or other data mining techniques. For example, the implementation of some interventions such as computer reminders for removal of catheters (both urinary and central line) and computerized antibiotic stewardship protocols may be helpful in decreasing infections. However, it is clear that electronic surveillance is not adequate. <sup>65,66</sup> It is not reasonable to believe that electronic surveillance without expert clinician oversight would ever become the standard for infection prevention. However, it is likely that healthcare information technologies will become increasingly used by IPs. It is also important to realize that implementation of new technologies is complex and often difficult. Indeed, with initial implementation of some technologies, there are often unintended consequences such as increased workload. <sup>67</sup> Understanding how these tools transform the role of the IP and establishing best practices will be important.

## International Perspective

Patient safety and reduction of HAIs is gaining global interest. <sup>68</sup> Internationally, though, the issues regarding staffing are different for the developed and developing countries.

## ISSUES FOR DEVELOPED COUNTRIES

The Antimicrobial Resistance Prevention and Control (ARPAC) study was conducted to ascertain the organization and policies of infection prevention and control programs in 169 acute care hospitals in 32 countries in Europe in 2001. <sup>69</sup> Of the hospitals in this study, 72 percent reported a formal infection prevention program and 90 percent reported the existence of a multidisciplinary infection prevention committee. The presence of infection prevention nurses was reported in 80 percent of the hospitals and varied by geographical region (100 percent in northern Europe to 54 percent in southeastern and central eastern Europe). The median staffing levels reported in the study were 2.33 infection prevention nurses per 1,000 beds and 0.94 infection prevention doctors. <sup>70</sup> Moreover, only 18 percent of the hospitals reported more than one infection prevention nurse per 250 beds and 69 percent of the hospitals reported lack of skilled staff as one of the problems in implementing infection control policies. These results show that staffing levels for infection prevention nurses are below recommended staffing standards. For example, the European Study Group on Nosocomial Infections estimated staffing requirements to be 1.8 infection prevention doctors and 4.2 infection prevention nurses per 1,000 beds, with an additional 3.3 personnel per 1,000 beds available for data management and administrative support. Similarly, a group of IPs and medical microbiologists convened in the Netherlands in 2007 determined that a minimum staffing of one IP FTE per 178 medical beds or one IP FTE per 5,000 admissions was needed to carry out infection control activities in acute care settings. <sup>71</sup> On a hopeful note, the median staffing levels reported in the ARPAC study are higher than the median ratios reported 5 years earlier in European hospitals. <sup>40</sup> Moreover, the ARPAC study results were discussed at the 2004 Consensus Conference, leading to development of recommendations that included ensuring that acute care hospitals have adequate infection prevention staffing, with the SENIC recommendations considered the minimum, establishing certified training in infection prevention, and removing barriers to the successful implementation of infection policies such as lack of isolation rooms and skilled staff. <sup>72</sup> In many European countries, infection prevention training is not formally certified as a medical specialty and may therefore vary widely. <sup>70</sup> This lack of standardization has been noted by the European Society of Clinical Microbiology and Infectious Diseases, which has published recommendations for training programs in infection prevention.<sup>73</sup>

The use of an infection prevention "link" nurse, which is defined as a nurse working on the ward who liaises with the infection prevention department, <sup>74</sup> is seen increasingly in European countries. For example, the ARPAC study shows that more than 46 percent of the study hospitals reported the presence of a link nurse. <sup>69</sup> The main role of link nurses is to "provide information to assist in the early detection of outbreaks of infection and to help increase awareness of infection prevention issues in their ward." <sup>74</sup> By being directly based in the wards and providing direct patient care, link nurses can help the wards to develop ownership of infection prevention and serve as a resource to their colleagues. <sup>74</sup> Several studies have shown the value of link nurses in influencing infection prevention practices at the ward level, <sup>75</sup> their usefulness in facilitating the collection of HAI data, <sup>76</sup> and their ability to provide education and help in the implementation of policies at the ward level. <sup>77</sup> Although the value of link nurses has been shown in many settings, operational difficulties such as high staff turnover and need

for sustained monitoring and support of the link program have been reported and necessitate further investigation. 74

## ISSUES FOR DEVELOPING COUNTRIES

The problems associated with reduction in HAIs and successful implementation of infection prevention and control programs are even more pronounced in developing countries. A recent report from the International Nosocomial Infection Control Consortium (INICC) indicates that rates of device-associated HAI are much higher in INICC ICUs compared to U.S. ICUs participating in the NHSN, even though use of devices is similar. 78 Some of the factors that are thought to play a role in these increased rates are

the scarce financial and administrative resources available for infection prevention in the majority of hospitals in developing countries, lack of laws directing the establishment of infection prevention and control programs, low nurse staffing ratios, and low compliance with hand hygiene guidelines. 79,80,81

Another problem that affects the health systems in developing countries is the migration of HCP within and between countries because of the increased demand in developed countries. More study is required to adequately assess this trend and to develop appropriate public policy responses.<sup>81</sup>

## Conclusions

There is not a set staffing ratio that is effective across multiple settings. It is clear that the role of the IP is changing, but it is not clear whether sufficient resources are being allocated to staffing. Monitoring the changing role of the IP in light of the changing healthcare delivery system and making efforts to determine what constitutes sufficient staffing will continue to be important and is an area for needed research.

## Supplemental Resources

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## **Section 2**

### **Epidemiology, Surveillance, Performance, and Patient Safety Measures**

# General Principles of Epidemiology

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## Abstract

*Epidemiology—the study of the frequency, distribution, cause, and control of disease in populations—forms the basis of all health-related studies. It provides the background for interventions to reduce transmission of infecting organisms, reduce the number of healthcare-associated infections, and protect healthcare providers from infection. Understanding the relationships of host, environment, and organism will aid the infection preventionist in designing studies to determine the cause of healthcare-associated infections and design interventions.*

## Key Concepts

- The primary purpose of epidemiology is to aid in the understanding of the cause of a disease by knowing its distribution; determinants in terms of person, place, and time; and natural history.
- Understanding the elements involved in the transmission of infection enables infection preventionists to develop strategies that target specific areas in the process.
- Selecting the appropriate study design is an essential step in answering questions important to the infection preventionist.
- The infection preventionist should understand the meaning of commonly used terms and know how to apply basic epidemiology skills.
- Correct presentation of data allows the infection preventionist to demonstrate outcomes and relationships in a manner that will likely encourage collaboration and support among stakeholders.

## Background

This chapter provides information about the epidemiological principles and methods used in the practice of infection surveillance, prevention, and control and shows that they are an important part of the discipline known as epidemiology.

The infectious disease process is a set of complex interrelationships of agent, host, and environment that has been studied by epidemiologists for more than a century. One goal of epidemiology is to understand the natural history of diseases and conditions to develop strategies for their prevention and control. Three closely interrelated components—distribution, determinants, and frequency—are integral to the principles and methods of epidemiology. By becoming familiar with these concepts, the infection preventionist (IP) will begin to develop and expand a knowledge base for interpreting data gathered within and outside the healthcare facility and for understanding the associations between risk factors and infection in different settings and how these findings can be used to reduce infection risks for patients and healthcare personnel (HCP). The Supplemental Resources cited at the end of this chapter reflect the breadth and depth of the discipline.

Epidemiology as a discipline incorporates the use of statistics to determine associations and test hypotheses. Examples used to explain formulas and calculations are drawn from familiar settings, yet the IP with little or no background in statistics is not expected to master the materials in this chapter without additional study. An expanded discussion about the statistics used in epidemiology is beyond the scope of this chapter.

Although information is provided about the theoretical basis for epidemiology and statistics, the principal goal of this chapter is to present practical information that will allow the IP to use epidemiological skills in day-to-day practice. Following completion of this chapter, the reader will have a better understanding of healthcare-associated infections (HAIs) within the total discipline of epidemiology and how principles of epidemiology can be applied to many practice issues.

## Basic Principles

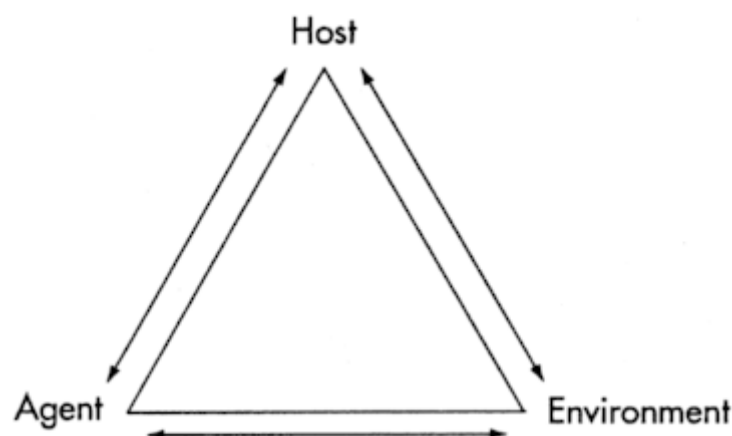
Epidemiology is the study of the distribution and determinants of disease and other conditions in human populations—both a body of knowledge and a method of study. Epidemiology encompasses the study of many factors that are detrimental to human health, including infectious diseases, chronic diseases such as cancer or heart disease, drug or alcohol abuse and their sequelae, violence, injury, and others.

Epidemiology, unlike clinical medicine, is population-based and is useful for describing health-related phenomena in groups of people. Epidemiological methods are used in the measurement of a disease, its determinants, and its distribution in a particular population in question before, during, and after an intervention. Therefore, epidemiology can be used in determining whether there is a problem in a population, risk factors for a disease, and whether there has been a change in disease outcome after an intervention. Although epidemiology studies groups of people rather than an individual patient, its principles are used widely in all areas of healthcare. Epidemiology provides information for community and preventive medicine, analysis of health assessments, safety programs, utilization review and management of resources, and health planning and forecasting. As an applied science, epidemiology is a professional discipline that encompasses all academic fields of study.

The primary purpose of epidemiology is to aid in the understanding of the cause of a disease by knowing its distribution; determinants in terms of person, place, and time; and natural history. This

information is also used in epidemiology to plan and evaluate interventions and prevention efforts more effectively. To this end, several approaches, or methodologies, are used in obtaining epidemiological information. These include observational studies, in which the natural course of events is observed, and experimental studies, in which the investigator actively intervenes to modify one or more factors. Observational studies may be either descriptive, in which events are described in terms of person, place, or time, or analytical, in which risk factors and trends are observed and compared. These methodologies are described in greater detail later.

To understand the interactions between risk factors and the development of disease, it is first important to understand the elements that cause disease. The "epidemiological triangle" model of disease (see Figure 10-1) consists of three elements: host, agent, and environment. The host is the human, whereas the environment consists of all external factors associated with the host. The agent may be a bacteria, virus, fungus, protozoan, helminth, or prion. In this model of dynamic interaction, change in any component alters the existing equilibrium. Change may increase or decrease the frequency of disease. Although this model is particularly useful in the study of infectious diseases, it is also applicable to other conditions.



**Figure 10-1.**

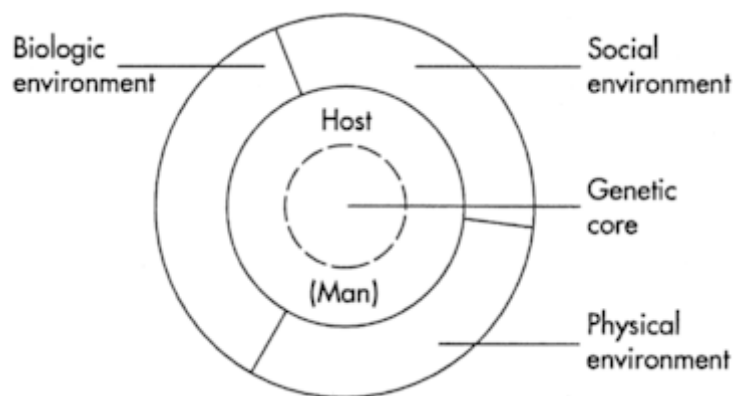
Epidemiologic triangle model of disease causation.

[View Image](#)



The "wheel" model (see Figure 10-2) consists of a hub (the host or human) with an inner core of genetic information. The environment surrounding the host is divided into three parts: physical, biological, and social. The size of each component is related to the disease process under consideration. For example, the genetic core is large for hereditary disease and small for childhood viral diseases. The emphasis in

this model is not the agent per se but on the interaction between the host and the environment and the agent and the environment.



**Figure 10-2.**

"Wheel" model of disease causation.

[View Image](#)



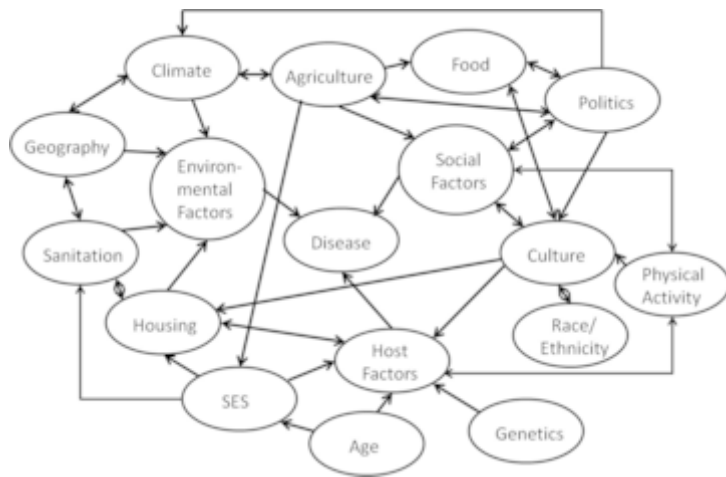
A third model for describing how disease occurs is the "web of causation" (see Figure 10-3). In this model there is an attempt to capture the more complex interactions between the biological (host), environmental, and social factors that contribute to disease. There is emphasis on the contributions of social and political aspects of human life and how these are interrelated to other contributing factors.

**Figure 10-3.**

"Web" model of disease causation.

[View Image](#)





## ASSOCIATION AND CAUSATION

Association occurs if, as one variable changes, there is a concomitant or resultant change in the quantity or quality of another variable. When a statistical association between a factor and a disease has been demonstrated, it may be of three types: artifactual (or spurious), indirect or noncausal, or causal. A certain number of associations will simply occur by chance, with the number of associations rising as a greater number of factors or variables are studied. This is known as *random error*. Artifactual associations may also be caused by errors in

study design or analysis, leading to the introduction of systematic error or *bias*. Bias in study design may be caused by instrument, observer, data collection method, case and control group selection (selection bias resulting in subject groups not being comparable), or other errors. Errors in analysis, including inappropriate choice of statistical test and underpowering of studies, may lead to bias. Failure to control for confounding variables in the study design or analysis may also result in artifactual associations. Bias and random error may also result in no association being seen when one actually exists.

Indirect or noncausal associations may result from the mixing of effects between the exposure, the disease, and a third factor, or confounding variable, that may be associated with the exposure and independently affect the outcome of interest. Confounding can lead to the assumption that there are differences that do not really exist or to the observation that there is no difference when one truly exists. Causal associations exist when evidence indicates that one factor is clearly shown to increase the probability of the occurrence of a disease. In a causal relationship, the reduction, or diminution, of a factor decreases the frequency of the disease being studied. This should not be confused with causality, which requires a number of conditions to be met, one of which is the presence of causal associations.

The scientific criteria for disease causation have their roots in Koch's postulates (Robert Koch, 1843–1910). Koch's postulates consist of four points:

1. The organism must always be found with the disease, in accordance with the clinical stage observed.
2. The organism must then be grown in pure culture from a diseased host.
3. The same disease must be reproduced when a pure culture of the organism is inoculated into a healthy susceptible host.
4. The organism must then be recovered from the experimentally infected host.

These postulates were originally accepted as an attempt to establish a causal relationship between microorganisms and disease processes. Although historically significant, as we have learned more about disease causation, it has become apparent that Koch's postulates cannot always be fulfilled (e.g., multicausal diseases, chronic diseases, some viral diseases). Koch himself accepted that not all of his criteria would be met in each case.

The currently used criteria for causality were developed by Austin Bradford Hill (1897–1991) and are known as Hill's criteria. These criteria use modern epidemiological methods to determine whether a

factor is causal for a given disease and are listed in Table 10-1. These criteria are equally applicable to infectious and noninfectious diseases.

1. *Strength of association*. The incidence of disease should be higher in those who are exposed to the factor under consideration than in those who are not exposed; that is, the stronger the association between an exposure and a disease, the more likely the exposure is to be causal. For example, lung cancer is common in those who smoke.
2. *Consistency* means that the association should be observed in numerous studies, preferably by different researchers using different research methodologies.
3. *Specificity* refers to an association between one factor and one disease, and this association is more likely to be causal. This criterion also refers to the extent to which the occurrence of one factor can be used to predict the occurrence of another (disease). In reality, such a one-to-one relationship is rare due to the multifactorial causes of most diseases and because, sometimes, the same factor(s) can cause more than one disease.
4. *Temporality* must also be addressed when determining cause of disease. Essentially, exposure to the hypothesized causal factor must precede the onset of disease.
5. The *biological gradient* is a dose-response relationship between increased exposure to a factor and increased likelihood of disease. For example, the longer one smokes, the more likely one is to develop lung cancer. If the association demonstrates a biological gradient between the factor (exposure) and effect (disease), the relationship is more likely to be causal.
6. The association in question should also be *biologically plausible* in light of current knowledge. This criterion may be the most elusive and variable of the nine. Because biological knowledge is ever expanding, lack of biological plausibility does not necessarily disprove a theoretical association.
7. There should be *coherence* between known information about the biological spectrum of the disease and the associated factor; that is, the association should be in accordance with other facts known about the natural history of the disease.
8. Associations derived from *experiments* add considerable weight to evidence supporting causal associations. These experiments can be animal model studies or clinical trials; however, although animal models may be helpful, many diseases do not manifest the same way in animals and humans.
9. Finally, if similar associations have been shown to be causal, by *analogy* the association is more likely to be causal. Determining causality may also help to determine at which points the natural history of a disease may be interrupted, so that prevention and control efforts are effective. It can also add information on the natural history of a disease.

**Table 10-1** Table 10-1. Hill’s Criteria for Causation

Strength
Consistency
Specificity
Temporality
Biological gradient
Plausibility
Coherence
Experiment



## Analogy

The association between *Shigella sonnei* and gastroenteritis provides an example of applying Hill's criteria to an infectious disease. Strength is demonstrated by disease occurrence among those exposed to the organism. The association between ingestion of *S. sonnei* and gastroenteritis has been demonstrated consistently in numerous studies by different investigators, although development of disease may not occur 100 percent of the time. Temporality is demonstrated because exposure to the organism precedes development of gastroenteritis and occurs within the correct incubation period. The biological gradient is evident because larger doses of *S. sonnei* are more likely to result in disease. *S. sonnei* is a biologically plausible cause of gastroenteritis, based on knowledge of its toxin production, and disease caused by *S. sonnei* is coherent with other facts known about gastroenteritis. In addition, experiments have shown that *S. sonnei* causes gastroenteritis and that other species of *Shigella* cause, analogously, similar disease. All this leads to the conclusion that there is a causal association between *S. sonnei* and gastroenteritis.

Applying the criteria for causality is not as straightforward when the etiology is not clear. The associations between toxic shock syndrome (TSS), *Staphylococcus aureus*, and tampon use pose such a problem. There is increased risk of disease in females who use tampons (strength), and most studies (consistency) have shown a relationship between *S. aureus* and TSS. Although other organisms can cause TSS, in no case has TSS associated with tampon use been associated with any other organism (specificity). However, in the initial stages of the investigation, the role of many other vaginal organisms was studied. The presence of *S. aureus* alone or tampons alone does not cause disease; a number of other factors are involved. No specific phage has been found that induces the production of the toxin implicated in TSS associated with tampon use. Colonization with *S. aureus* probably precedes TSS disease and also cases of TSS in patients with postoperative wounds (temporality). It is postulated that continuous, more than intermittent (biological gradient), use of superabsorbent tampons allows a large number of organisms to persist in the vaginal canal. Plausibility and coherence is demonstrated by the knowledge that some *S. aureus* strains produce toxins that can cause toxic poisoning and a shock syndrome. Experiments with *S. aureus* toxins have shown that these toxins produce disease. TSS is consistent with a toxin-induced illness, and the disease is consistent with our knowledge of *S. aureus* diseases, such as staphylococcal food poisoning and scalded skin syndrome, both of which are caused by *S. aureus* toxins (analogy). Based on Hill's criteria, the conclusion reached is that a causal association exists between *S. aureus* and TSS; however, a simple causal relationship does not exist between superabsorbent tampons and TSS. Superabsorbent tampons are one of many risk factors for TSS.

There are difficulties associated with the use of criteria for causality. Although certain study designs (e.g., random-allocation clinical trials) produce data that are used to prove causality, in fact, even with all criteria met, it is rarely possible to explain all the factors contributing to a specific disease entity. For example, tuberculosis has been classically viewed as meeting all of the criteria to satisfy Koch's postulates. Yet recent approaches to the study of this disease clearly indicate that socialization and lifestyle, and coinfection with human immunodeficiency virus (HIV), have an impact on the risk for development of tuberculosis. In addition, if a well-described disease with a clearly defined etiological agent is subject to a "third cause" (i.e., an unmeasurable factor), it follows that diseases that are less well described or lack clearly defined etiological agents will frequently be subjected to challenges about undetermined contributing factors. An example is the challenge to the causal association of smoking and lung cancer. The tobacco industry maintains that the association between smoking and lung cancer is the result of some yet to be defined variable and that the association with smoking is only a spurious result. The tobacco industry uses the argument that not all people who develop lung cancer are

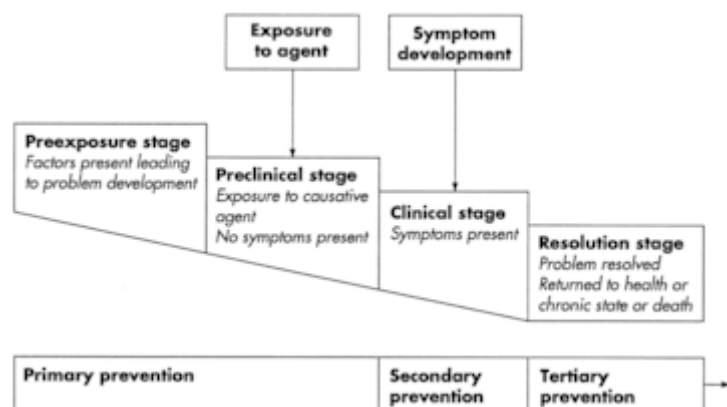
smokers. (However, epidemiological research and analyses of many studies by Doll and Peto have demonstrated that smoking meets Hill's criteria for causality of lung cancer and a number of other diseases.)

## Uses of Epidemiology in Healthcare

One of the uses of epidemiology is to apply information gathered to various forms of disease prevention. There are three categories of prevention, which are sometimes referred to as Leavell's levels: primary, secondary, and tertiary. Primary prevention includes health promotion programs, such as wellness programs, and specific protections, such as immunization. The goal is the complete prevention of a disease before any manifestation of that disease occurs, preferably before the occurrence of any preclinical changes that may lead to disease. Secondary prevention refers to early diagnosis and treatment and includes skin testing in tuberculosis and mammograms for early detection of breast cancer. Secondary prevention also involves methods that may limit disability, such as stopping smoking in people with chronic bronchitis. The emphasis is on preventing further deterioration by intervention as early in the disease course as possible. Tertiary prevention occurs after disease is well established and deals with sequelae of disease. Examples of tertiary prevention include rehabilitation and organ transplantation.

Applications of disease prevention, using information gathered with epidemiological studies, are wide-ranging. Prevention efforts occur in community and healthcare facility-based healthcare delivery systems. Forecasting for future needs in both treating illness and promoting health is important in healthcare planning. Prevention forms a part of occupational and environmental programs in the workplace, the ambient environment, and in the reduction of workers' risks. Noninfectious events, both acute (e.g., auto accidents, poisonings) and chronic (e.g., heart diseases, malignant neoplasms), have been the target of many prevention programs.

Prevention programs also have a place in infectious diseases. Some acute infections with the potential for spread into the community, such as measles, rubella or other childhood diseases, are addressed with vaccine programs. Infections that may become chronic, such as tuberculosis, are prevented by limiting exposure to those who are contagious and by treatment of those who have active disease. Prevention of HAIs requires intensive staff education. It is also important to understand the stages of the natural history of disease and the relationship to primary, secondary, and tertiary levels of prevention (see Figure 10-4). Decisions about prevention will, in part, be dependent on the stage of a given disease at which interventions can be made. Ideally, primary prevention should be carried out, but this is not necessarily practical or possible.



**Figure 10-4.**

Stages of the natural history of a condition and their relationship to primary, secondary, and tertiary prevention. (Redrawn from Clark MJ. *Nursing in the Community*. Norwalk, CT: Appleton & Lange, 1992.)

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Prevention strategies in healthcare infection prevention are wide-ranging and depend on the disease in question and what information is available to the practitioner. Prevention

strategies to reduce the risk of transmission—including barrier precautions, immunizations of HCP, and cleaning, sterilizing, and disinfecting—are designed to prevent the occurrence of disease and, therefore, form primary prevention measures. Forecasting for future health needs as the general population ages must lead to infection prevention practices that deal with health problems of the elderly. Occupational and environmental health exposures may be prevented in hospital personnel through programs and training, such as the use of barrier methods to prevent transmission of bloodborne pathogens or appropriate barriers to prevent tuberculosis transmission. Prevention of HAIs also requires an understanding of the impact that chronic diseases and underlying conditions (e.g., immunosuppression, chronic obstructive pulmonary disease) have on increasing the risk of HAIs.

## USEFUL TERMS IN INFECTIOUS DISEASE EPIDEMIOLOGY

A basic knowledge of terminology used in infectious disease epidemiology makes both understanding and communication easier. Listed here are a number of terms and their definitions that will be useful to the infection preventionist.

*Incidence*: the number of new cases of a given disease in a given time period. For example, the number of newly diagnosed cases of active tuberculosis in a calendar year in a given county is the incidence of tuberculosis in that county.

*Prevalence*: the number of existent cases of a given disease at a given time. For example, the number of active tuberculosis cases in the same county at the midpoint of the calendar year.

*Endemic*: the usual incidence of a given disease within a geographical area during a specified time period.

*Epidemic*: an excess over the expected incidence of disease within a given geographical area during a specified time period. If the expected number of cases of a disease in a county is 8 per year, and 16 occur in 1 year, this indicates an epidemic. It should be noted that an epidemic is not defined on the absolute number of cases but on the number of cases in comparison to what is expected.

*Pandemic*: an epidemic spread over a wide geographical area, across countries or continents.

*Outbreak*: synonymous with epidemic but a term often preferred when dealing with the public. It may not evoke the same fearful response as the term *epidemic*.

*Enzootic*: the usual presence of disease among animals within a geographical area. The animals may serve as a reservoir for a zoonotic disease.

*Epizootic*: an excess over the expected extent of disease within an animal population in a geographical area during a specified time period.

*Zoonosis*: a disease transmitted from animals to humans (e.g., cat scratch fever, psittacosis).

*Reservoir*: place in which an infectious agent can survive but may or may not multiply, for example, *Pseudomonas* in nebulizers and Hepatitis B on the surface of a hemodialysis machine. HCP may also be reservoirs for a number of HAI organisms.

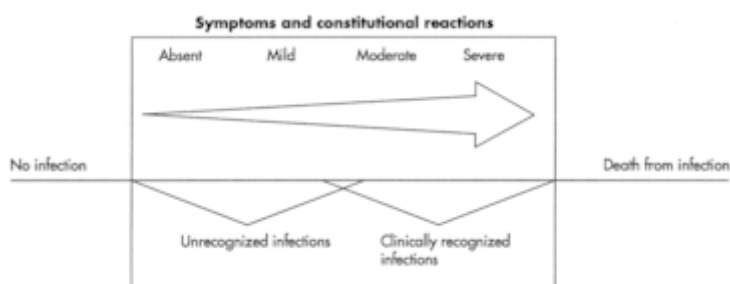
*Fomite*: an inanimate object on which organisms may exist for some period of time. For example, the hemodialysis machine in the previous example.

*Herd immunity*: the resistance of a group to invasion and to spread of an infectious agent, based on the immunity of a high proportion of individual members of the group.

**Risk:** the probability or likelihood of an event occurring.

**Risk factor:** a characteristic, behavior, or experience that increases the probability of developing a negative health status (e.g., disease, infection).

Infection is the entry into and multiplication of an infectious agent in the tissues of the host and tissue damage resulting in apparent or unapparent changes in the host (see Figure 10-5). Unapparent, asymptomatic, or subclinical infections run a course similar to that of clinical disease but below the threshold of discernible clinical symptoms. Apparent, clinical, or symptomatic infections result in clinical signs and symptoms of a recognizable disease process.



**Figure 10-5.**

Infectious disease spectrum: various host responses to infection by an infectious agent. (Redrawn from Centers for Disease Control and Prevention. *Principles of Disease Control—A Three-Day Training Course*. Atlanta, GA: CDC, 1992).

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HAIs are those that are not present at the time of admission to the hospital but are temporally associated with admission to or a procedure performed in a healthcare facility. An infection present at the time of admission may also be healthcare-associated if it is related to a recent hospitalization. Sometimes it is difficult to determine if an infection is healthcare-associated, particularly if information on previous hospitalizations is not available. In contrast to HAIs are community-acquired infections, those infections present on admission with no association to a recent hospitalization.

In addition to understanding the concepts of healthcare-associated and community-acquired infection, it is important that the IP understands the concept of colonization. Colonization is the presence of microorganisms in or on a host with growth and multiplication but without tissue invasion or damage. A thorough understanding of this concept is essential in the planning and implantation of epidemiological studies in a healthcare infection prevention and control program. Confusing colonization with infection can lead to spurious associations that may lead to expensive, ineffective, and time-consuming interventions. However, the IP must also realize that colonization may become infection when changes in the host occur and that, for some disease entities, a colonized host may spread organisms to other patients.

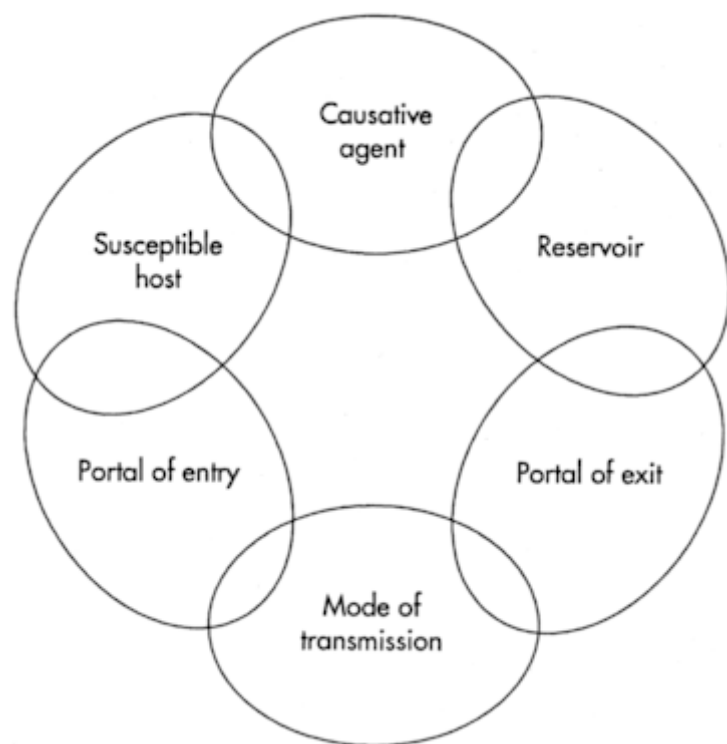
## THE CHAIN OF INFECTION

The infection process can be described as a chain of infection (see Figure 10-6). Understanding this chain must precede the breaking of its links, which leads to prevention of infection. Each component, or link, in this chain is connected to another link in the chain.

The causative agent of infection can be thought of as the first link in the chain. A causative agent is a biological, physical, or chemical entity capable of causing disease. Biological agents may be bacteria, viruses, fungi, protozoa, helminths, or prions. Some biological agents have characteristics that make them more successful in causing infection. To cause disease, these agents must be invasive enough to enter tissues, multiply, and cause some amount of damage. They must be sufficiently virulent to be pathogenic. The infectious dose (the number of organisms required to cause disease) and how viable an organism is in the free state also determines whether infection will develop. Host specificity affects

organism success as well. An organism causing disease only in marmosets probably will not have success in causing infection in humans.

Organisms may also have high rates of antigenic variation that help to circumvent host-immune responses. This is the case with influenza, in which the outer protein antigens change from year to year, necessitating the yearly development of a new influenza vaccine. The ability to develop antimicrobial resistance also provides the organism with an advantage to continue causing infection, despite what was previously appropriate treatment.



**Figure 10-6.**

The chain of infection. Components of the infectious disease process.

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The next link in the chain is the reservoir—that is, a place in which an infectious agent can survive but may or may not multiply. There are three common reservoirs of interest: humans, animals, and environment. Common reservoirs associated with HAIs include patients, HCP, and healthcare equipment and environment. Human reservoirs are generally cases with the disease in question, either acute clinical cases or subclinical (asymptomatic) cases, or carriers. A carrier is a person who shows no recognizable signs or symptoms of a disease but is capable of spreading disease to others, such as HCP with methicillin-resistant *Staphylococcus aureus* (MRSA) nasal colonization. During the prodromal phase of some diseases, the

organism is multiplying but has not yet caused signs and symptoms of the disease and may be transmitted to others. Convalescent carriers are those who have recovered from the disease but still have organisms present that can be transmitted. For example, a patient with cholera may continue to shed bacteria in the stool for several weeks after diarrhea has subsided. Chronic or sustained carriers may continue to have organisms present for very long periods of time. "Typhoid" Mary Malone is an example of a chronic carrier; *Salmonella typhi* may continue to exist in the gallbladder of a significant number of people who have recovered from typhoid. From the gallbladder, it is shed through the gastrointestinal tract and may infect those who come in contact with the carrier's feces. Carriers can live long and healthy lives with the organism present. There are also intermittent carriers who periodically shed organisms, such as *S. aureus*. Subclinical cases and carriers present a particular risk of transmission to susceptible hosts in the healthcare setting because they are less likely to be recognized. There may be no indication that they are ill or that they may be infectious. Precautionary measures to prevent transmission are less likely to be instituted because illness is not apparent.

The next link in the chain of infection is the portal of exit—that is, the path by which an infectious agent leaves the reservoir. Portals of exit and portals of entry are listed in Table 10-2.

The mode of transmission, the next link in the chain of infection, is the method by which the organism reaches a susceptible host. Contact transmission is of particular importance in the healthcare setting. Direct contact is person-to-person spread with actual physical contact occurring between a source and a



susceptible host (e.g., fecal-oral spread of Hepatitis A virus). Indirect contact may occur when a patient comes in contact with a contaminated intermediate object or fomite. An example in the healthcare setting would be a bed rail contaminated with small particles of stool. Some organisms, such as MRSA or vancomycin-resistant enterococci (VRE), may survive for days or weeks in the environment and be available for direct or indirect contact transmission. Droplet transmission occurs when the infectious agent spends only a brief period passing through air and can be inhaled at that time. Droplets may arise from speaking, coughing, or sneezing. Because heavy droplets travel only a short distance, generally a meter (about 3 feet) or less, the infected person and susceptible host need to be relatively close to each other for efficient transmission to occur.

Common vehicles, such as food and water, may also transmit infectious agents. In active direct transmission with a common source, the organism first replicates in the vehicle, producing a larger dose of the organism, which is then ingested, such as *Salmonella* in raw chicken. Passive or indirect transmission may occur if the organism is simply present. No increase in loading dose is necessary. An example of passive transmission by common vehicle is food contaminated with Hepatitis A virus. The virus does not replicate in the food, but when the food is ingested, it may cause infection.

Airborne spread is an efficient mode of transmission and may involve varying distances between the source and host. The most efficient means of airborne transmission is by droplet nuclei. Droplet nuclei are very small, about 1 to 5  $\mu\text{m}$ , and can be suspended in air for extended periods of time. The size of the particle makes it ideal for inhalation because it is small enough to reach the respiratory tree without being swept up by cilia. The small size of the particle and its ability to remain suspended in air also means that droplet nuclei may spread through ventilation systems. Tuberculosis is the classic example of a disease spread by droplet nuclei.

**Table 10-2** Table 10-2. Portals of Entry and Exit

Portals of Exit	Portals of Entry
Respiratory tract	Respiratory tract
Genitourinary tract	Genitourinary tract
Gastrointestinal tract	Gastrointestinal tract
Skin/mucous membrane	Skin/mucous membrane
Transplacental (mother to fetus)	Transplacental (fetus to mother)
Blood	Parenteral (percutaneous via blood)

Vectors, such as insects, also may transmit infectious organisms, although this method of transmission is of less importance in the hospital setting in most industrialized nations. External vectorborne transmission is the mechanical transfer of microorganisms by a vector, such as a fly on food. Internal vectorborne transmission involves transfer of infectious material directly from the vector into the new host, such as occurs in mosquitoes and malaria, fleas and plague, and louseborne typhus. The vector may simply harbor the infectious organism with no biological interaction taking place, or the agent may actually undergo changes within the vector (e.g., malaria parasites require that part of their life cycle take place within a mosquito).

The portal of entry is the means by which an infectious agent enters the susceptible host. Portals of entry associated with human hosts are listed in Table 10-2. The susceptible host is the next link in the chain of infection. In addition to the characteristics of the susceptible host shown in Table 10-3, the

susceptible host has several nonspecific defense mechanisms that may modify the risks of becoming infected and developing disease. Normal (endogenous) flora in the host may protect it from other infectious organisms, and the host's natural antibodies attack some invading organisms. Natural barriers to the entry of organisms include (1) skin and mucous membranes, which provide mechanical barriers; (2) cilia of the respiratory tract and cough mechanism, which clear material from the respiratory structures; (3) gastric acid of the stomach, which helps destroy ingested pathogens; (4) mechanical flushing, which protects the genitourinary tract; and (5) tear flushing, which helps to protect the eye. Finally, good nutritional status protects the host overall.

Salmonellosis can be studied in terms of the chain of infection. The causative agent of salmonellosis is *Salmonella*, a bacterium that can survive in the free state and generally has an infective dose of 106 organisms or greater if the host has normal gastric acidity. Some strains of *Salmonella typhi* have much smaller infective doses. The reservoirs for *Salmonella* include humans, both carriers and active cases, and animals (including poultry, cattle, reptiles, and others). There are also environmental reservoirs for *Salmonella*, including contaminated food products, untreated sewage, and biological waste products (e.g., fertilizers, bone meal). The portals of exit are the gastrointestinal tract and, to a lesser extent, the genitourinary tract. Modes of transmission include both contact and common vehicles. Direct contact with the organism may occur while changing diapers or while handling raw poultry. Indirect contact by the hands of personnel may happen after handling an incontinent patient and then tube feeding the next patient without washing hands. Use of gloves should never replace hand hygiene because, although the gloves may reduce the likelihood of transmission, they may have microtears, and contaminated matter may get under the wrist area of the glove. Common vehicle transmission, in this case contaminated food, is a well-known mode of transmission for *Salmonella*. The portal of entry is the gastrointestinal tract and, although everyone is susceptible at some level, the elderly, the young, and those with decreased stomach acid are especially vulnerable.

**Table 10-3** Table 10-3. Host Characteristics Influencing Susceptibility to and Severity of Disease

Characteristic	Examples
Age	"Childhood diseases" are seen more frequently in children, whereas chronic diseases, such as heart disease or chronic obstructive pulmonary disease, occur more frequently in older patients
Sex	Reproductive diseases are sex-specific
Ethnicity	Tay-Sachs disease in Jews of European descent
Socioeconomic status	Ability to purchase healthcare services, food purchasing
Marital status	Some studies of stress-related diseases have shown marital status to be a factor influencing susceptibility
Lifestyle	Homelessness increases susceptibility due to poor nutrition and exposure
Heredity	Sickle cell anemia influences susceptibility
Nutritional status	Inadequate nutrition reduces immune function
Occupation	Coal miners are at risk for black lung
Immunization status	Those who have not been vaccinated for measles are at risk for the disease
Diagnostic/therapeutic procedures	Transplant patients have increased risk of infection
Medications	Steroid use increases risk of infection



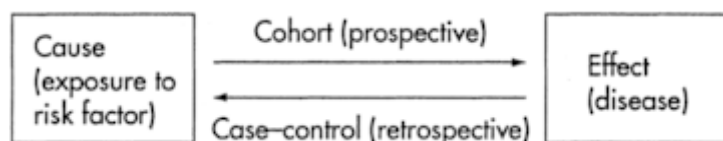
Pregnancy	Tuberculosis-positive women who are pregnant are more likely to reactivate
Trauma	Injury may provide portal of entry for organisms and triggers inflammatory response that may increase risk of infection

Control of infectious diseases involves breaking the chain of infection by altering the host, the environment, or the agent. In the *Salmonella* example, measures directed at the agent and the reservoir includes proper storage, handling, and cooking of food and properly treating sewage to inactivate the organism. Educating cases and carriers about hygiene may also break the transmission of disease at the reservoir link in the chain of infection. The susceptible host breaks the chain through caution in cooking, eating, and hygiene habits. Environmental measures include restricting food handlers with disease, treatment of carriers (reservoir link), wearing of gloves when contact with stool or contaminated items is likely, and proper handwashing for patients and personnel providing care (transmission link).

## INTERRUPTING THE CHAIN OF INFECTION: EPIDEMIOLOGICAL STUDY DESIGN

Epidemiology uses tools to determine risk factors for disease, and these may help to identify links in the chain of infection that may be interrupted or broken. Primary study designs used in the healthcare setting are described as prospective or retrospective. These studies are commonly used in relation to cohort and case-control studies, respectively. The prospective and retrospective designs result in observational studies, in which the investigator does not manipulate any components, but simply observes characteristics and outcomes. These studies describe the subjects in terms of person, place, and time. Essentially, they look at the "who," "where," and "when" of disease occurrence in an effort to determine the "why."

In prospective or cohort studies, data are gathered over time. In this study design, a group of subjects with a known exposure status for the risk factor(s) of interest are followed over time to determine which of the subjects develops disease. These subjects form a cohort going through time together. Experimental studies are also prospective in nature. Data are gathered as subjects move from the present into the future while being followed up by the researcher. In contrast, case-control studies are referred to as retrospective—moving backward from disease state to risk factor by first identifying persons with the disease and then measuring their degree of exposure to the risk factor(s) of interest in the past (see Figure 10-7).



**Figure 10-7.**

Contrasting prospective and retrospective investigation.

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Sometimes the terms prospective and retrospective are used in a temporal, rather than conceptual, sense. A cohort study that measures disease frequency in the present and among persons with a known exposure in the past is commonly called a "retrospective cohort study" (see Figure 10-8). Study and research designs are described more fully in Chapters [19](#) and [20](#).

## ADVANTAGES AND DISADVANTAGES

Both cohort and case-control studies have advantages and disadvantages. Retrospective studies use data already available, such as patient charts or laboratory databases. They also require relatively small numbers of subjects relative to cohort studies because a sufficient number of cases are already included

in the study, that is, the researcher does not have to wait for enough cases to develop to perform an analysis. This makes the case-control method useful for disease states that occur rarely. It also makes retrospective studies less expensive because fewer total subjects may be required for analysis, and data are already available. These studies also take less time than prospective studies because the cases are already identified and are commonly used in healthcare epidemiology and infection prevention to identify causes of outbreaks. However, case-control studies are dependent on the completeness of records, and it may be difficult to select an appropriate control group. Retrospective studies are used to get information about past events and are subject to recall bias because they rely on the memory of subjects and others for information on exposure.

Prospective, or cohort, studies are usually more expensive than case-control studies in part because they take longer and generally require more study subjects. Long follow-up periods may be required while waiting for disease to occur in sufficient numbers for analysis. Attrition may result from long follow-up periods, reducing the sample size of a study. Traditionally, cohort studies are considered to have fewer bias issues than case-control studies because they avoid the subjectivity involved in collecting after-the-fact exposure data from persons already affected by disease. They also yield incidence rates because the population at risk has already been identified and can yield associations between risk factors and disease that were not anticipated. Cohort studies generally carry more weight and tend to be used when controversial retrospective findings need to be verified.

## RECOGNIZING OUTCOME-RELATED EVENTS

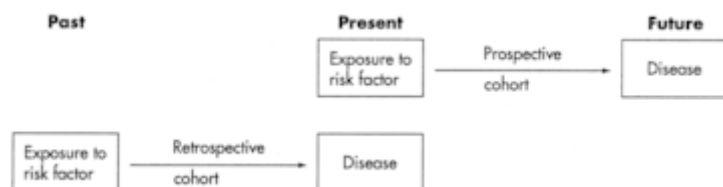
Once epidemiological studies have been performed, it is important to recognize the outcomes of those studies to apply knowledge gained. Outcome events are useful in evaluation of an infection prevention and control program and may include decreased rates of infection, length of stay, days in intensive care units, and other measures. Modification of behaviors by HCP and learned skills by personnel can be measured by looking at outcomes. Changes in HAI rates can be determined (although extreme caution must be used in the interpretation of results because some HAIs are not preventable by known interventions). Changes in policies and procedures may result in changes in outcomes or may result from outcome differences. Being able to show outcomes from studies may result in priority modifications in the future for the infection prevention program or the facility.


## DATA PRESENTATION

Once data have been gathered and analyzed, they must be presented clearly and concisely, greatly helping others to understand the study, why it was done, and the outcomes. Data are generally presented graphically in one of three forms: tables, graphs, or charts. All well-constructed tables, graphs, and charts present a limited amount of information that is easily understood, and, ideally, each can stand alone. Too much information simply becomes confusing, defeating the purpose of graphically presenting the data. Each presentation graphic must have a complete title that describes the contents in terms of the event being studied, the population being studied, and the place and time of study. For example, a complete title might be, "Reported cases of bacteremia in surgical intensive care unit patients, in Hospital X, in March, 2004." This title tells the reader much more than the alternative "Bacteremia in the SICU." When preparing tables, graphs, or charts, it is helpful to indicate the date they were prepared. This may be important because data often change over the course of an outbreak investigation, and dating graphics will help the researcher keep current and track changes. The source of data must be identified if data from an outside source are used in the table, graph, or chart.

### Figure 10-8.

Retrospective and prospective cohort.



A few definitions of terms used [View Image](#)  components of tables, graphs, and charts may be helpful. A *cell* is the space in a table, graph, or chart in which data are entered. The *class interval* is the subgrouping of values for any given epidemiological variable, such as age or sex. For example, "age" may be grouped into

two class intervals: "younger than 15 years old" and "15 years and older." *Continuous data* are data for which there are an infinite number of possible values between the minimum and maximum values. Examples include age, weight, and temperature. This is in contrast to *discrete data*, which can be counted only in whole numbers, such as number of children. A *coordinate* is one of a pair of locators used to specify a particular point, for example, the x and y coordinates on a graph.

## TABLES

A table is a set of data arranged in rows and columns (Figure 10-9). Tables are used to present the frequency with which some event occurs and to present this information in different categories or subdivisions of a variable. Well-constructed tables are simple; ideally, they do not try to present more than three factors at a time. Readable tables have a clear, concise title that answers who, what, where, when, and how questions, that is, they provide information about person, place, and time. Each column and row should be labeled and the column and row totals shown, if they are used. Codes, abbreviations, and symbols should be explained in footnotes. Sources of information gathered from outside the institution or used for comparison should be cited.

Age group (years)	Number of cases
0-4	1,242
5-14	1,081
15-24	2,482
25-44	8,153
45-64	10,916
65+	7,124
Total	30,998

Source: HHS, PHS, CDC, Reported Morbidity and Mortality in the United States, 1995. Weekly Report for Year Ending December 28, 1995. Vol. 34, No. 53, page 12.

Figure 10-9.

Elements of a well-constructed t [View Image](#) 

## GRAPHS

Graphs are a method of showing quantitative data using a system of coordinates (Figure 10-10). A well-constructed graph consists of two sets of lines that intersect at right angles. Each axis (line) has a scale measurement and a label. By convention, the horizontal (x) axis reflects the variable time in whatever interval is being used (year, month, quarter, day, etc.)

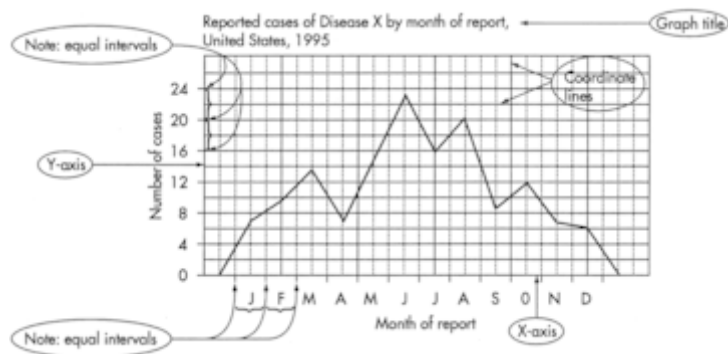
when time is to be presented. The vertical (y) axis usually reflects the frequency of occurrence of an event (e.g., the number of cases of disease) or the proportion (e.g., percent, cases per 1,000 patient days) with the event. More than one factor or variable can be shown on a graph, but each should be clearly differentiated by a legend or key. It is important to remember that each graph should be simple and self-explanatory.

Figure 10-10.

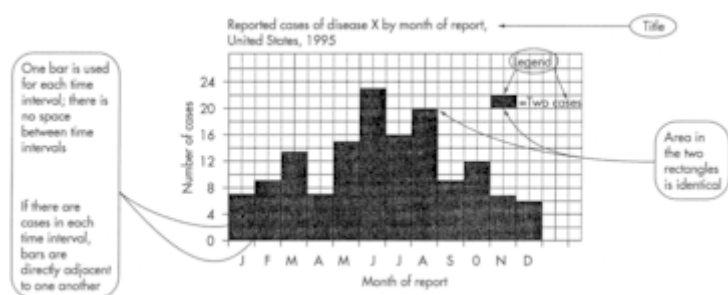
Elements of a well-constructed graph.

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There are several forms of graphs used in the presentation of epidemiological data. The arithmetic line graph uses equal distances along the y axis to represent equal quantities anywhere on that axis (see Figure 10-10). The semi-logarithmic scale line graph uses a y-axis measured in logarithms of units. This



A frequency polygon is similar to a line graph, but each coordinate point is represented by a point displayed on the graph with straight lines connecting them. A frequency polygon will provide the same data information as a histogram.



**Figure 10-11.**

Elements of a properly constructed

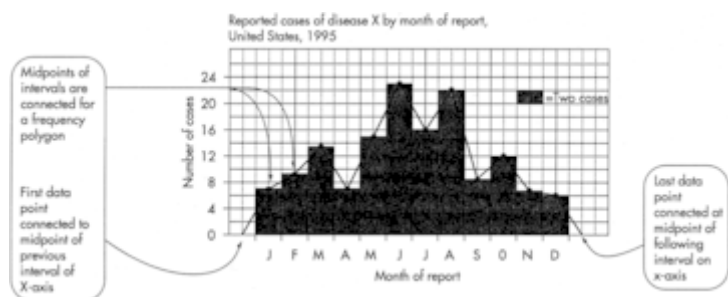
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## CHARTS

A chart is a method of illustrating information using only one coordinate. Charts are used to compare magnitudes of different events and to compare parts of a total picture. Types of charts

include bar charts, geographical coordinate charts, pictograms, and pie charts. Bar charts use bars to depict the event being studied (see Figure 10-12). The bars are the same column width and, unlike histograms, are separated by spaces. Bar charts can be used to compare magnitudes, show frequency distributions, and show time-series data. The pictogram is a variation of a bar chart that uses a series of small identifying symbols to represent the data. Geographical coordinate charts represent the occurrence of events using maps. Spot maps use dots or symbols at each location where an event took place (e.g., patient rooms with a dot for each patient with a disease). An area map uses shaded or coded areas to show the distributions of some conditions (e.g., color codes of wards based on the number of patients in the area with a given condition). The pie chart is used to represent proportions in the form of percents by assigning them to wedge-shaped portions of a circle for comparison so that the entire "pie" is 100 percent (see Figure 10-13). A pie chart is not appropriate when there are many wedges—limit the number to five or six.



**Figure 10-12.**

Comparison of a histogram and its corresponding frequency distribution

[View Image](#)

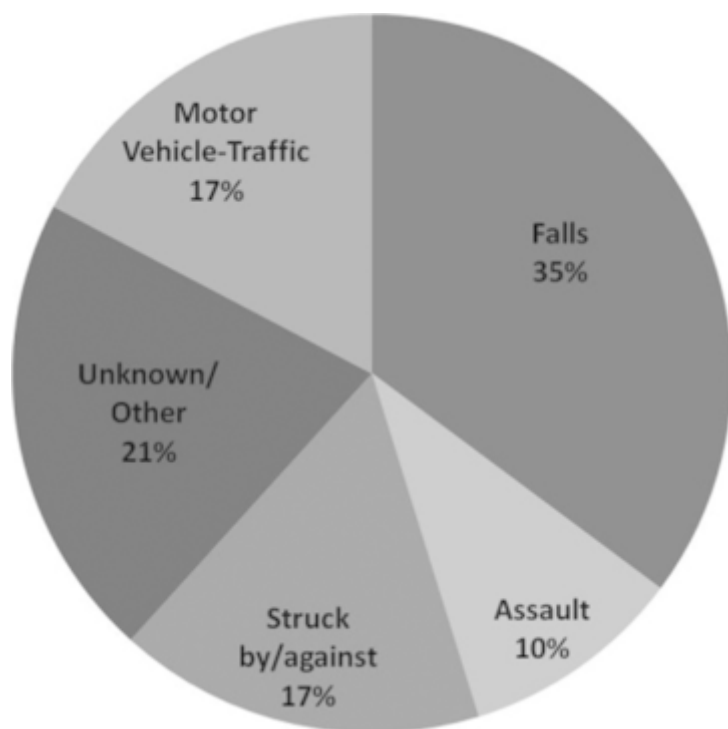


U-charts are gaining popularity in infection prevention. These provide statistical process control (SPC) information to help monitor quality assurance and are most often used for monitoring length of stay and infection rates.

These charts use calculated upper and lower limits over time, and the statistical or other (Excel) programs can be used to generate rates, limits, averages, and such for use in constructing control charts. Essentially, the control chart, in this case the U-chart, provides a range of expected variation



about a mean (centerline) and the upper and lower limits (upper control limit and lower control limit) beyond which the process is considered out of control. These charts can be particularly useful in conveying changes in rates over time and identifying points in time when infection rates or other processes are outside the expected range. The control chart is specifically designed to show when a process is out of control, unstable, or unpredictable. Processes that are out of control (i.e., increasing infection rate) can be identified, and prevention efforts put in place to regain control or increase stability. The U-chart is one of several SPC charts available but is useful in infection prevention because there can be more than one error (i.e., infection) per patient taken into account. The caveat to SPC charts is that they can be less stable with small denominators. Control charts are discussed more fully and examples provided in Chapter **14. Process Control Charts**.



**Figure 10-13.**

Estimated average percentage of annual traumatic brain injuries by external causes in the United States, 2002–2006. (From Centers for Disease Control and Prevention. *Traumatic Brain Injury in the US*. CDC Website. 2012. Available at:

[http://www.cdc.gov/Features/dsTBI\\_Braininjury/.](http://www.cdc.gov/Features/dsTBI_Braininjury/))

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## Conclusions

In summary, an infection preventionist's basic understanding of epidemiological methods is crucial for a well-functioning infection prevention and control program. These methods form the basis of all studies and outbreak investigations conducted and in the assessment of programs developed. Understanding basic epidemiological methods will lead to better study design and studies that are more likely to provide accurate and comparable information for creating change to reduce HAI rates and clear and concise data presentation so that changes in rates, causes of outbreaks, and so forth can be easily understood by healthcare facility administration and HCP.

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## Surveillance

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## Abstract

*Surveillance is an essential component of an effective infection prevention and control program. This chapter discusses the history, evolution, and use of surveillance programs in healthcare settings. It outlines the steps that should be used when designing and evaluating a surveillance program; emphasizes the importance of using sound epidemiological and statistical principles; and stresses the use of surveillance data to improve the quality of healthcare. It reviews factors that affect surveillance programs in healthcare facilities, such as the changing healthcare delivery system, emerging and reemerging infectious diseases, and mandatory reporting requirements. This chapter also identifies new developments, future trends, and international issues related to surveillance in healthcare settings.*

## Key Concepts

- Surveillance programs should be based on sound epidemiological and statistical principles.
- Surveillance methodology continues to evolve as the healthcare delivery system shifts outside of the traditional acute care hospital.
- A surveillance program should be designed in accordance with current recommended practices and should consist of defined elements.
- Surveillance activities should support a system that can identify risk factors for infection and other adverse events, implement risk-reduction measures, and monitor the effectiveness of interventions.
- Surveillance plays a critical role in identifying outbreaks, emerging infectious diseases, multidrug-resistant organisms, and bioterrorist events so that infection prevention measures can be instituted.
- Surveillance programs in healthcare organizations should be integrated to include infection prevention, performance improvement, patient safety, and public health activities.
- Mandatory and public reporting requirements significantly affect surveillance programs.

## Background

Surveillance can be defined as "a comprehensive method of measuring outcomes and related processes of care, analyzing the data, and providing information to members of the healthcare team to assist in improving those outcomes."<sup>1</sup> Surveillance is an essential component of an effective infection prevention and control program.<sup>2,3</sup>

In 1958, in response to nationwide outbreaks of *Staphylococcus aureus* infections in hospitals, the American Hospital Association recommended that hospitals implement a healthcare-associated infection (HAI) surveillance program.<sup>4</sup> In the 1960s, the Centers for Disease Control and Prevention (CDC) recommended that hospital-based infection prevention and control programs incorporate surveillance activities and, in 1976, The Joint Commission (TJC) first included infection surveillance, prevention, and control standards in its requirements for hospital accreditation.<sup>5</sup> The Study on the Efficacy of Nosocomial Infection Control (SENIC Project) provided scientific evidence that hospitals that had strong surveillance programs coupled with strong prevention and control programs were able to improve patient outcomes by reducing HAI rates.<sup>6</sup> Since the publication of the SENIC Project results in 1985, much has been published regarding the use of surveillance to monitor healthcare processes and practices and HAIs.

Since the 1980s, the healthcare delivery system has dramatically shifted outside of the traditional acute care hospital, resulting in an increasing need for surveillance programs in other healthcare settings.<sup>3,7</sup> In response to this shift, infection prevention organizations have published recommendations for surveillance in out-of-hospital settings.<sup>1,3,8</sup> State, federal, and accrediting agencies now require infection surveillance and prevention programs in a variety of healthcare settings, including hospitals, long-term care (LTC), rehabilitation, ambulatory surgery, dialysis, home care, mental health, and corrections facilities.

Since the early 2000s in response to demands for more public information on HAIs, state and federal government agencies have increasingly mandated the reporting of infection-related data. The implementation of these requirements has created resource and technological challenges.<sup>9</sup> Other factors affecting surveillance programs include shorter hospital stays, the aging of the population, increased use of invasive procedures and devices, more acutely ill patient and resident populations, healthcare personnel shortages, emerging and reemerging infectious diseases, and the threat of bioterrorism.<sup>7</sup> As healthcare practices evolve, new diseases emerge, antimicrobial resistance spreads and mandatory reporting requirements increase, new surveillance methodologies are needed to meet the changing environment.

Surveillance can be used for the following purposes:

- Determine baseline and endemic rates of occurrence of a disease or event
- Detect and investigate clusters or outbreaks
- Assess the effectiveness of prevention and control measures
- Monitor the occurrence of adverse outcomes to identify potential risk factors
- Provide information that can be used by an organization to target performance improvement activities
- Measure the efficacy of interventional and performance improvement efforts

- Observe practices, such as hand hygiene, central line insertion, and sterilizer performance monitoring, to promote compliance with recommendations and standards
- Detect and report notifiable diseases to the health department
- Identify organisms and diseases of epidemiological importance, such as multidrug-resistant organisms (MDROs) and tuberculosis, to prevent their spread
- Ensure compliance with requirements of federal regulators, such as the Occupational Safety and Health Administration (OSHA) and the Centers for Medicare & Medicaid Services (CMS)
- Ensure compliance with state regulations and state mandatory reporting requirements
- Meet requirements of accrediting agencies, such as The Joint Commission and the Accreditation Association for Ambulatory Health Care
- Provide information for the education of healthcare personnel
- Monitor injuries and identify risk factors for injuries of personnel
- Detect a bioterrorist event or an emerging infectious disease
- Provide data to conduct a facility risk assessment.

Surveillance data have been used successfully in a variety of healthcare settings to reduce the occurrence of infections when used to identify risk factors, implement risk reduction measures, and monitor the effectiveness of interventions.<sup>6,10,11,12,13,14,15,16,17,18,19</sup>

This chapter reviews the basic principles, terms, and definitions used in surveillance programs in healthcare settings. It also discusses surveillance methodologies, key elements of a surveillance program, using surveillance data for performance improvement, the use of information technology, new developments, future trends, international issues, and provides a list of supplemental resources for obtaining additional information.

## Basic Principles

Surveillance programs should be based on sound epidemiological and statistical principles. If surveillance data are properly collected and analyzed, they can provide information that can be used to improve the quality and outcomes of healthcare and to promote public health. Those who are responsible for implementing and assessing surveillance programs should be familiar with the general principles of epidemiology that are discussed in other chapters of this text.

## DEFINITIONS

The following are definitions of terms, as used in healthcare surveillance. Many of the definitions are adapted or taken from the glossary in *Principles of Epidemiology in Public Health Practice: An Introduction to Applied Epidemiology and Biostatistics*, third edition.<sup>20</sup>

**Attack rate:** an incidence proportion, rather than a true rate, that is used to measure the frequency of new cases of a disease or condition in a specific population during a limited period. It is usually used to describe the proportion of the population that develops a disease or condition during an outbreak.

**Baseline:** the number or value used as the basis for comparison.

**Case:** an instance of a particular disease, injury, or other health condition that meets selected criteria.

*Case definition:* a set of uniformly applied criteria for determining whether a person should be identified as having a particular disease, injury, or other health condition; usually specifies clinical, laboratory, and other diagnostic criteria.

*Cluster:* a group of cases that occurs closely related in time and place without regard to whether the number of cases is more than expected (often the expected number is not known).

*Denominator:* the lower portion of a fraction used to calculate a rate or ratio.

*Distribution:* frequency and pattern of an event in a population.

*Endemic:* usual presence of a disease or condition in a specific population or geographical area.

*Epidemic:* the occurrence of more cases of a disease than expected in a given area or among a specific group of individuals during a specified time period; synonym of outbreak.

*Epidemiology:* the study of the distribution and determinates of health conditions or events in specified populations and the application of this study to the control of health problems.

*Incidence rate:* a measure of the frequency with which an event occurs in a population over a defined time period. The numerator is the number of new cases occurring during the defined time period, and the denominator is the population at risk.

*Outcome:* the result of care or performance activities.

*Numerator:* the upper portion of a fraction used to calculate a rate or ratio. In surveillance, it is usually the number of cases of a disease or event being studied.

*Population:* the total number of individuals in a specified place or group.

*Prevalence:* the number of cases or events or conditions occurring in a population.

*Prevalence rate:* the proportion of persons in a population who have a particular disease or condition at a specified point in time (point prevalence) or over a specified period (period prevalence).

*Proportion:* a type of ratio in which the values in the numerator are included in (i.e., are a subset of) the denominator.

*Process:* the series of steps or activities taken to achieve an outcome.

*Rate:* an expression of the frequency with which an event occurs in a defined population per unit of time. In healthcare surveillance, it is often used more casually to refer to proportions that are not truly rates (e.g., attack rate or incidence density rate).

*Ratio:* the value obtained by dividing one quantity by another.

*Sensitivity:* the ability of a test, case definition, or surveillance system to identify true cases or persons who have the health condition of interest (i.e., the proportion of persons with a health condition that are correctly identified by a test or case definition as having the health condition).

*Specificity:* the ability of a test, case definition, or surveillance system to exclude persons who do not have the health condition of interest (i.e., the proportion of persons without a health condition that are correctly identified by a test or case definition as not having the health condition).

**Validity:** the degree to which a measurement, test, study, or other data collection method actually measures or detects what it is intended to measure.

## BASIC STATISTICAL MEASURES USED FOR SURVEILLANCE

Common statistical measurements used in surveillance programs in the healthcare setting are measures of frequency (e.g., rates, ratios, and proportions), measures of central tendency (e.g., mean and median), measures of dispersion (e.g., standard deviation), and percentiles. Because statistical methods are discussed in detail in other chapters of this text, they are only described briefly here.

### *MEASURES OF FREQUENCY*

Rates, ratios, and proportions are used to measure the occurrence and risk of an event in a specific population during a given period. These frequency measures are based on the same formula:

$x \div y \times 10^n$ , where the numerator and the denominator represent the two groups being compared and the multiplier  $10^n$  is used to transform the result into a number that is larger than one.

### *RATIOS AND PROPORTIONS*

A ratio is a fraction in which the values in the numerator ( $x$ ) may or may not be included in the denominator ( $y$ ). A ratio can be used to express a relationship between two independent groups. The device utilization ratio used in the National Healthcare Safety Network (NHSN) is determined by dividing the number of device-days by the number of patient-days.<sup>21</sup> This is an example of a ratio in which the values in the numerator (device-days) are independent of the values in the denominator (patient-days).

A proportion is a ratio in which the population in the numerator is a subset of the population in the denominator. A proportion is frequently expressed as a percentage.

Examples using ratios and proportions:

In a 12-month period, six patients in a critical care unit developed a ventilator-associated condition (VAC); four cases are female and two are male.

1. The ratio of female cases to male cases is determined using the formula  $x \div y \times 10^n$  in which  $x$  is 4,  $y$  is 2, and  $10^n$  is 1 ( $n = 0$ ). The ratio of females to males would be  $4 \div 2 \times 1 = 2 \div 1$  or 2:1. Thus, there are two females for every male, or twice as many females as males who developed a VAC. In this ratio, the values in the numerator (females) are not included in the denominator (males).
2. The proportion of the six VAC cases that are male would be calculated using the formula  $x \div y \times 10^n$  in which  $x$  is 2,  $y$  is 6, and  $n$  is 0. The proportion of cases that are male would be  $2 \div 6 \times 1 = 1 \div 3$  or 1:3. Thus, one-third, or one of every three, VAC cases are male. This proportion can be expressed as a percentage if  $10^n$  is 100 ( $n = 2$ ) where  $2 \div 6 \times 100 = 33$  percent. In a proportion, the values in the numerator are always a subset of those in the denominator.

### *RATES*

A rate is a measure of the occurrence of an event in a defined population in a defined time. A rate has a time dimension. Rates can be used to track trends and to monitor changes in the frequency of an event in a population from one time period to another (e.g., the occurrence of bloodstream infections in patients in an intensive care unit [ICU] before and after interventions implemented to reduce the risk of

infection). The most commonly used rates in surveillance programs for healthcare settings are incidence, attack, and prevalence.

An incidence rate measures the occurrence of new cases or events in a specific population during a given time period. The formula for calculating an incidence rate is  $x \div y \times 10^n$  where  $x$  (the numerator) is the number of new cases or events in a population during a given time period,  $y$  (the denominator) is the number in the population at risk during that time period, and  $10^n$  is used to transform the result into a number that is larger than one. The numerator in an incidence rate calculation is always the number of new cases in a specified period. However, the denominator differs depending on the study being conducted. <sup>20</sup> For surveillance in healthcare facilities, the denominator is frequently the number of the average population observed in a specified time period or the cumulative person-time the population was at risk in a specified time period. In a person-time incidence rate, the denominator is the sum of the time each person was at risk in a specified time period, totaled for all persons. Examples of incidence rate calculations using cumulative person-time:

1. In March, there were three central line-associated bloodstream infections (CLABSI) and 491 central line-days in an ICU. The calculation for the CLABSI rate in the ICU in March is the number of CLABSI in ICU patients in March  $\div$  the number of central line-days in ICU patients in March  $\times 1,000$ , or  $3 \div 491 \times 1,000 = 6.1$ . In this example,  $10^n = 1,000$  ( $n = 3$ ) so that the result is larger than one. This rate is expressed as 6.1 CLABSI per 1,000 central line-days in the ICU in March.
2. In June, there were two resident falls in an LTC unit that had 275 resident-days. The calculation for the fall rate would be the number of falls in the LTC unit in June  $\div$  the number of resident-days in the LTC unit in June  $\times 1,000$ , or  $2 \div 275 \times 1,000 = 7.3$ . In this example, the rate is expressed as 7.3 falls per 1,000 resident-days in the LTC unit in June.

An attack rate, which is actually an incidence proportion rather than a true rate, is generally used to describe the frequency of cases during an outbreak. <sup>20</sup> The formula is  $x \div y \times 10^n$  where  $x$  (the numerator) is the number of new cases or events in a population during a given time period,  $y$  (the denominator) is the number in the population at risk during that time period, and the result is usually expressed as cases per 100 population, or as a percentage (i.e., where  $n = 2$  and  $10^n = 100$ ).

Example attack rate calculation:

Eleven of 46 individuals developed acute gastroenteritis within 24 hours of eating at a luncheon. The attack rate for gastroenteritis among the luncheon attendees would be calculated by dividing the number of individuals with gastroenteritis ( $x = 11$ ) by the number of those that ate at the luncheon ( $y = 46$ ) and multiplying by  $10^2$  or 100 (to provide a percentage). The attack rate is  $11 \div 46 \times 100 = 23.9$  percent.

Prevalence measures the occurrence of existing (old and new) cases in a specific population during a given time period. The formula for prevalence is the number of existing cases in a population during a specific time period  $\div$  number in that population during that time period  $\times 10^n$ .

Examples of prevalence calculation:

On April 1, a study was done in an LTC facility to determine the point prevalence of residents being treated with an antibiotic. On that day, there were 120 residents and 62 were on antibiotic therapy. The point prevalence of residents being treated with an antibiotic is calculated by dividing the number of residents receiving antibiotic therapy ( $x = 62$ ) by the number of residents in the facility on that day ( $y =$



120) and multiplying by  $10^2$  or 100 (to provide a percentage). The point prevalence is  $62 \div 120 \times 100 = 51.7$  percent.

### *MEASURES OF CENTRAL TENDENCY*

Measures of central tendency describe the values around the middle of a set of data. 20 Two measures of central tendency used in healthcare surveillance are the arithmetic mean and the median. The mean is the mathematical average of the values in a set of data. Although the mean is commonly used, it is important to remember that its value is affected by outliers (extremely low or high values). The median is the middle value in a ranked set of data. Because half of the measurements in the data set lie below the median and half of the measurements lie above it, the value of the median is not affected by outliers.

### *MEASURES OF DISPERSION*

Measures of dispersion measure the distribution of a set of data around its mean (mathematical average). Commonly used measures of dispersion in hospital epidemiology are the range, deviation, variance, and standard deviation.

The range is the difference between the smallest value and the largest value in a set of data. The deviation is the difference between an individual value in a data set and the mean (average) for the set. Variance is the deviation around the mean of a distribution. The standard deviation is a measure that reflects the distribution of values around the mean.

### *PERCENTILES*

Percentiles are used to indicate the relative position of a measurement with respect to other measurements in a set of data. The median is the 50th percentile in a distribution of numbers because half of the values in the distribution are lower and half are higher than the median value. In addition to the median, percentiles that are commonly used for reporting surveillance data are the 10th, 25th, 75th, and 90th percentiles.

The CDC NHSN reports percentile distributions for device-associated infection rates and device utilization ratios among participating facilities. 21 Healthcare organizations that collect and analyze their data using NHSN methodology can use the NHSN data for comparison and benchmarking. An appendix in the NHSN Data Summary Reports for the device-associated module provides instructions on how to interpret percentiles of infection rates or device utilization ratios. 21 Additional information on how to use and calculate these statistical measures can be found in other chapters of this text and in the Supplemental Resources section at the end of this chapter.

## **SURVEILLANCE METHODOLOGIES**

### *TOTAL (OR WHOLE) HOUSE SURVEILLANCE*

In total (or whole) house surveillance, all HAIs are monitored in the entire population of a healthcare facility. When total house surveillance is conducted, an overall facility infection rate should not be calculated; rather, rates should be calculated for specific HAIs in defined populations in the facility, such as CLABSI in an ICU or surgical site infections (SSIs) related to a specific operative procedure. Overall rates have long been discouraged by most experts because crude overall rates are not sensitive enough to identify potential problems and therefore cannot be used to target performance improvement



activities. <sup>22,23,24</sup> In addition, because overall rates are not adjusted for specific infection or injury risks, they are not appropriate for measuring trends over time, making comparisons between groups either within a facility or between facilities, or benchmarking. <sup>23</sup> Although it is ideal to monitor all infections in the entire population in a facility, many healthcare organizations do not have the technical and personnel resources needed to do so, and targeted surveillance is generally conducted.

### *TARGETED SURVEILLANCE*

In the 1990s, the CDC shifted the National Nosocomial Infections Surveillance/NHSN system away from total hospital surveillance to focus on targeted surveillance in defined populations. <sup>25</sup> Targeted surveillance focuses on particular care units (e.g., a nursery or ICU), infections related to medical devices (e.g., intravascular and urinary catheters), invasive procedures (e.g., surgery), and organisms of epidemiological significance (e.g., methicillin-resistant *Staphylococcus aureus*[MRSA]). <sup>21,26</sup> Targeted surveillance usually focuses on high-risk, high-volume procedures and on those HAIs and adverse outcomes that are potentially preventable.<sup>1,24,26</sup> **The CDC Targeted Assessment for Prevention (TAP)** strategy utilizes NHSN data to target prevention strategies specific to each facility and allows the CDC to identify facilities with the greatest need for improvement. TAP reports include the metric, Cumulative Attributable Difference (CAD) which yields a specific number of infections that must be prevented in order to reach established HAI reduction goals. CDC encourages Infection Preventionists to utilize specific TAP reports and CAD metric that represent concrete prevention goals that are linked to standardized infection rates (SIR).

### *COMBINATION SURVEILLANCE STRATEGY*

In practice, many infection prevention and control programs use a combination of targeted and modified total house surveillance. Many programs monitor targeted events that occur in a defined population, such as catheter-associated urinary tract infections (CAUTIs) in an ICU, while concurrently monitoring selected HAIs and laboratory reports from facilitywide locations. For instance, laboratory reports can be monitored housewide to detect the following: MDROs (e.g., MRSA and vancomycin-resistant enterococci [VRE]), reportable diseases, organisms of epidemiological importance, and clusters that may indicate an outbreak or breakdown of infection prevention practices (e.g., several cases of diarrhea associated with *Clostridium difficile* on a medical care unit).

## ELEMENTS OF AN EFFECTIVE SURVEILLANCE PROGRAM: SURVEILLANCE PROGRAM DESIGN

Much has been published about developing and evaluating surveillance programs.<sup>1,8,22,23,27</sup> The following steps should be taken when designing a surveillance program for a healthcare setting.

### *SELECT THE SURVEILLANCE METHODOLOGY*

A surveillance program may measure all infections (i.e., total surveillance) or may be focused (targeted) on events selected by an organization. <sup>22,26</sup> As discussed previously, when total house surveillance is done, an overall infection rate should not be calculated. <sup>22,23</sup>

### *ASSESS AND DEFINE THE POPULATION(S) TO BE STUDIED*

Each organization should assess its patient, resident, and employee populations and identify those that have the greatest risk for infection or other adverse outcome.<sup>1,22</sup> This is done by assessing the types of persons served (e.g., newborn, pediatric, adult, geriatric), healthcare services provided (e.g., medical, surgical, rehabilitation, LTC, ambulatory care, long-term acute care), surgical and other invasive procedures performed, and the conditions and diseases present in the population.

### *CHOOSE THE EVENTS TO MONITOR*

One of the most important steps in designing a surveillance program is the selection of appropriate health-related events to monitor.<sup>1,22</sup> Surveillance programs should measure outcomes of healthcare, processes of healthcare, and selected events of importance to the organization.<sup>1,22</sup> Some monitored events should focus on personnel.

The events chosen should be based on the following:

- Type of healthcare setting
- Populations being studied (including patients, residents, and healthcare personnel)
- Procedures performed and services provided
- Acuity of care
- A risk assessment that identifies risk factors for infection and other adverse events in the populations studied
- State, federal, accrediting, and other relevant agency requirements, including mandatory reporting requirements
- Available resources, both personnel and nonpersonnel
- Availability of the data required
- Public health needs
- Performance improvement initiatives
- Organizational objectives

It is common to monitor high-volume, high-risk events in a specific population. Monitor events that have the potential to provide information that can be used to improve outcomes and infection prevention practices. Examples of outcome events that may be monitored include the following:

- HAIs (e.g., bloodstream, urinary tract, pneumonia, surgical site, conjunctivitis, upper respiratory tract, or local intravenous site)
- Infection or colonization with a specific organism (e.g., *C. difficile*, MRSA, VRE, or other MDROs, respiratory syncytial virus [RSV] or rotavirus)
- Phlebitis related to peripheral intravascular therapy
- Pyrogenic reaction or pus, redness, or increased swelling at a dialysis vascular access site in hemodialysis patients
- Sharps injuries and communicable disease or blood/body fluid exposures in healthcare personnel
- Tuberculin skin test conversion rates in healthcare personnel
- Influenza immunization rates in personnel, residents, or patients
- Hepatitis B immunization rates in personnel

- Examples of process events include the following:
- Personnel compliance with infection prevention protocols, such as:
  - Standard precautions
  - Isolation precautions
  - Central line insertion, maintenance, and removal
  - Urinary catheter insertion, care, and removal
  - Safe injection and medication handling practices
  - Tuberculin skin testing
  - Hand hygiene
  - Instrument processing
  - Sterilization quality assurance testing
  - Environmental cleaning and disinfection
  - Communicable disease reporting
  - Antimicrobial prescribing and administration
  - Installing and maintaining barriers during construction and renovation projects

Examples of other events of significance that may be monitored include the following:

- Occurrence of reportable diseases and conditions
- Communicable and potentially communicable diseases in personnel
- Organisms or syndromes indicative of a bioterrorist event
- Results of quality assurance testing (e.g., monitoring of negative airflow in airborne infection isolation rooms, biological monitoring of sterilizers, and testing of high-level disinfectants)
- Admission of a patient or resident known to be infected or colonized with an MDRO

An effort should be made to select events that have validated, nationally available benchmark data that can be used for meaningful comparison, such as the NHSN and the Vermont Oxford Network for monitoring the medical care of newborns.

If rates are to be calculated, both the number of cases (i.e., persons who have the condition) and the number in the total population at risk for that condition must be identifiable. Rates, rather than raw numbers, must be used to accurately track trends over time.

Select events that incorporate a risk adjustment or risk stratification method whenever possible.<sup>1,21,22</sup>

For instance, the CDC NHSN event for CAUTI measures the development of a UTI associated with the risk of an indwelling urinary catheter in a defined population. For many years, patients in the NHSN SSI event module were stratified using a basic risk index based on duration of the surgical procedure, wound classification, and American Society of Anesthesiologists (ASA) score.<sup>28</sup> The NHSN SSI event module now uses procedure-specific risk models that incorporate additional risk factors such as gender, age, emergency, trauma, general anesthesia, medical school affiliation, number of hospital beds, endoscope, and outpatient.<sup>29,30</sup>

## *DETERMINE TIME PERIOD FOR OBSERVATION*

Collect surveillance data for each indicator consistently and for a defined period, such as a month, quarter, or year. It is difficult to interpret rates for events that rarely occur and procedures that are infrequently performed. Therefore, if uncommon events are measured and rates are calculated, it is necessary to use an observation period that is long enough to accumulate a sufficient number of events for the measurement to be valid.

### *IDENTIFY SURVEILLANCE CRITERIA (CASE DEFINITIONS)*

To accurately trend surveillance data over time within a facility, or compare rates between facilities, surveillance criteria (i.e., case definitions) must be consistently used to determine the presence of an HAI, occurrence of an event, or compliance with a process. If a case definition is changed, this should be noted in the surveillance report because the number of cases identified will likely change and the rate will be affected. Use criteria that reflect generally accepted definitions of the disease or event being monitored. Criteria have been published for defining HAIs in a variety of healthcare settings, including hospitals, LTC, and home care.<sup>30,31,32,33</sup> In the United States, the majority of healthcare facilities, and many government mandatory reporting programs, use the NHSN surveillance criteria and methodology.<sup>34</sup>

Individuals who conduct surveillance activities and identify HAI cases must apply surveillance criteria precisely. It should be noted that criteria used to define a case for surveillance purposes may be different than criteria used clinically for diagnosis and treatment. This is because surveillance definitions, such as those used in the NHSN, were developed for epidemiologic surveillance and not for clinical diagnosis. For instance, the NHSN surveillance criteria used to identify a *central line-associated* bloodstream infection can differ from the clinical criteria used to diagnose and treat a *catheter-related* bloodstream infection.<sup>35,36</sup> Therefore, a patient may fit the surveillance criteria for a CLABSI but may not be clinically diagnosed as having a catheter-related infection.

### *IDENTIFY DATA ELEMENTS TO BE COLLECTED*

The data elements that should be collected depend on the event being monitored and the statistical measures used to analyze the data. To use time and personnel resources efficiently, data collection should be limited only to those elements that are needed to identify a case and determine whether the case criteria are met for the condition or event being studied.

Data elements that may be collected include the following.

For an infectious event:

1. Case name; sex; age, unique identifier such as medical record or account number; unit or location in the facility; physician name and service; date of admission; date of onset of infection; type of infection; and date of discharge, transfer, or death
2. Information needed to determine whether the case definition is met: results of laboratory and diagnostic tests specified in the case definition, and dates performed; sites and dates cultured and organisms isolated; antibiotic susceptibility of significant isolates; and clinical signs and symptoms specific for the infection being monitored
3. Risk factors for the infection being monitored: host factors such as underlying conditions and diseases; surgical procedure and date performed; surgeon; use of intravascular catheters, including date of insertion, duration of use (vascular catheter-days), catheter type and body site; use of a urinary catheter, including date of insertion and duration of use (urinary catheter-days); mechanical ventilation and dates and duration of use (ventilator-days)

For a noninfectious event:

Case name; sex; age; unique identifier such as medical record or account number; unit or location in the facility; physician name and service; date of admission; primary diagnosis; date, time, and location of event; outcome (e.g., severity of injury); personnel involved; risk factors for the event; and date of discharge, transfer, or death.

#### *DETERMINE METHODS FOR DATA ANALYSIS*

Before data collection is initiated, the statistical measures that will be used to analyze the data must be determined so the requisite data can be collected. If rates or ratios will be calculated, the values corresponding to each numerator and denominator must be defined, and the appropriate data needed to calculate each rate or ratio must be collected.

Whenever possible, data should be expressed as rates or ratios that are calculated using the same methodology as a nationally validated surveillance system. This allows an organization to compare its rates with another organization or a recognized benchmark. For instance, if ventilator-associated events (VAEs) are monitored using the NHSN criteria and methodology, both the number of cases in a specified population that fit the VAE criteria (numerator data) and the total number of ventilator-days in that population (denominator data) must be identified to calculate VAE rates that can be properly compared with NHSN data.<sup>37</sup>

#### *DETERMINE METHODS FOR DATA COLLECTION AND MANAGEMENT*

Data may be collected concurrently (while a person is still under the care of the organization) or retrospectively (closed-record review after discharge).<sup>22</sup> The advantages of concurrent surveillance are as follows: data collectors may interview caregivers or observe the patient or resident if the chart does not include the information needed to fulfill the case criteria; immediate prevention and control measures, such as isolation precautions, may be instituted; clusters and outbreaks can be detected in a timely manner; and infection prevention personnel are available to identify and correct potential problems and provide education to personnel, visitors, and patients or residents. The disadvantages of concurrent surveillance are the time involved in locating records on a medical care unit (if paper records are being used) and incomplete medical records. The major advantage of retrospective review is that the medical record is more complete. The disadvantage of retrospective surveillance is that important findings, such as the identification of an outbreak, may be delayed and missing information may not be obtainable after discharge.

Sources of surveillance data include the following:

- Medical records (paper and electronic)
- Daily reports generated by the laboratory (e.g., microbiology, immunology, and serology results)
- Daily list of admissions, including diagnosis
- Monthly reports of patient-days and census data, by unit
- Nursing care plan (Kardex or computerized plan)
- Interviews with caregivers
- List of patients or residents on isolation precautions
- List of prescribed medications from the pharmacy
- Test results from the radiology department

- Incident reports
- Employee health reports of injuries, needlesticks, communicable diseases, and exposures
- Procedure and activity logs from the respiratory therapy department, operating room, and medical care units
- Reports from others who review medical records, such as performance improvement personnel
- Reports from caregivers
- Observations of care processes

Identify and use existing electronic databases and other sources of information. Whenever possible, arrange to have data downloaded directly into a computerized surveillance database so they can be efficiently manipulated and analyzed. Surveillance personnel can often accomplish this by working with an organization's information services department.

Ensure that personnel who are responsible for collecting and managing surveillance data have adequate training in reviewing medical records, interpreting clinical notes, applying standardized criteria for identifying cases, and using appropriate statistical and risk adjustment methods. Personnel should also be proficient in using computer tools and technology (especially electronic records, spreadsheets, and databases) to collect, enter, store, manage, and analyze data.<sup>1,2,3</sup>

Collect data using standardized data collection forms. These should be designed to collect only those elements needed to identify a case and determine if the case criteria are met for the condition or event being studied.<sup>8</sup> To facilitate rapid data collection, a form should be designed so that data elements (e.g., yes/no, procedures, treatments, and risk factors) can be circled, checked, or otherwise selected. Limit narrative entries as much as possible. The data collection forms used in the NHSN are available on the Internet ([www.cdc.gov/nhsn](http://www.cdc.gov/nhsn)) and can be used as-is or as a guide in designing a form for a specific event. Whenever possible, collect data via information technology and have it downloaded into an accessible database.

### *DESIGN AN INTERPRETIVE SURVEILLANCE REPORT*

Develop written reports to provide a mechanism to interpret and disseminate surveillance data and establish time lines for distributing the reports. Use surveillance findings to stimulate performance improvement activities. Tables, graphs, and charts are effective tools for organizing, summarizing, and visually displaying data and should be used when applicable. Tailor the format and level of detail in each report to the intended audience.

A surveillance report should:

1. Define the event, population, setting, and time period studied (e.g., SSI in patients undergoing coronary artery bypass graft in hospital A from January 2013 to December 2013).
2. State the criteria used for defining a case (e.g., NHSN criteria for SSI).
3. Specify the number of cases or events identified and the number in the population studied (e.g., 2 SSIs in 179 coronary artery bypass graft procedures performed).
4. Explain the methodology used to identify cases (e.g., case reports from personnel and review of medical records and laboratory results).
5. Identify the statistical methods and calculations used, when appropriate (e.g., fall rate on 2 North in April = number of falls on 2 North in April divided by number of resident-days on 2 North in

April multiplied by 1,000. The April rate is 3 falls &divide; 414 resident-days &times; 1,000 = 7.2 falls per 1,000 resident-days).

6. State the purpose for conducting surveillance (e.g., to identify risk factors for infection so that measures can be implemented to prevent infections from occurring).
7. Interpret the findings in a manner that is understandable to those who read the report.
8. Describe any actions taken and recommendations made for prevention and control measures.
9. Identify the author and date of the report.
10. Identify the recipients of the report.

### *IDENTIFY RECIPIENTS OF THE SURVEILLANCE REPORT*

Disseminate the report to those managers and healthcare providers in the organization that can use the findings to identify and implement evidence-based infection prevention practices and improve outcomes.

26

### *DEVELOP A WRITTEN SURVEILLANCE PLAN*

A written surveillance plan can be incorporated into an organization's infection prevention and control plan or can be a separate document. It should describe the following:

- Type of healthcare setting, services provided, and populations served
- Surveillance program purpose, goals, and objectives
- Results of the organization's risk assessment
- Events monitored and criteria used
- Reason for selecting each event (outcome, process, and other)
- Methodology used for case identification, data collection, and analysis
- Description of applicable mandatory reporting requirements of state, federal, and other relevant agencies
- Reports generated and to whom they are provided
- Process and frequency used to evaluate the surveillance program

## **SURVEILLANCE PROGRAM EVALUATION**

Periodically evaluate the surveillance program to assess its usefulness and ability to meet the organization's objectives, and make revisions as needed. Compare the program's structure and activities with current evidence-based practices and published recommendations for surveillance programs in similar settings.<sup>1,8,23,26</sup> Identify and incorporate the latest requirements of state, federal, accrediting, and other relevant agencies.

A surveillance program should be able to support a system that can prevent as many infections and other adverse events as possible with the resources available.

When assessing the surveillance program ask the following:

- Does it incorporate all of the elements of an effective surveillance program described in the above section under Program Design?
- Are data collected, managed, analyzed, and reported by knowledgeable personnel qualified by training and experience?



- Is the program being used to monitor and improve outcomes and processes?
- Are the quality and accuracy of surveillance data periodically evaluated and validated?
- Is the surveillance methodology periodically evaluated and validated?
- Are appropriate statistical methods used when comparing data internally over time?
- Are appropriate statistical methods used when comparing data with external benchmarks?
- Have information technology resources been identified?
- Is information technology being used to collect, store, manage, and analyze data as much as possible?
- Has the program demonstrated that it can accomplish the following:
  - Detect infections, injuries, or other events in a timely manner
  - Identify trends signaling changes in the occurrence of an event
  - Detect outbreaks and clusters of infection
  - Identify risk factors associated with infection or other adverse event
  - Provide an estimate of the magnitude of the event being monitored
  - Assess the effectiveness of prevention and control efforts
  - Lead to improved practices by healthcare providers and other personnel

A healthcare organization must also assess whether or not its surveillance program has adequate resources required to meet both the needs of the organization and the requirements of state, federal, and accrediting agencies. Evaluate the adequacy of the following:

- Ability of the infection preventionist (IP) to effectively manage the program (e.g., competency, training, and information technology skills)
- Number of staff to fulfill the needs of the organization
- Personnel access to, and use of, appropriate information resources, including the organization's databases, email, and the Internet
- Provision for ongoing infection prevention staff training
- Availability of office supplies and reference materials
- Availability of related services (e.g., secretarial, information technology, and laboratory support)

Provide written documentation of the surveillance program evaluation, including the assessment and allocation of personnel and nonpersonnel resources.

## SURVEILLANCE IN NONHOSPITAL HEALTHCARE SETTINGS

Although the majority of literature to date has focused on the acute care hospital, information on surveillance programs has been published for a variety of nonhospital healthcare settings: LTC,<sup>8,32,38,39,40,41</sup> ambulatory surgery, <sup>42,43,44,45,46</sup> outpatient hemodialysis, <sup>47,48,49,50,51</sup> physician's offices and clinics, <sup>52,53,54</sup> and home care. <sup>55,56,57,58</sup> Because surveillance methodologies evolve as the healthcare system changes, review current literature and practices before evaluating or developing a surveillance program in any healthcare setting.

## USING INFORMATION TECHNOLOGY

### *INFORMATION TECHNOLOGY AND THE INFECTION PREVENTIONIST*

The ability to use information technology—including word processing, spreadsheet, database, and graphics programs, the Internet, and email—is a basic requirement for the IP. At a minimum, IPs should subscribe to email discussion and announcement groups, such as those from the CDC, health departments, and professional organizations, such as the Association for Professionals in Infection Control and Epidemiology (APIC). These mailings inform subscribers about a variety of topics, including the occurrence of disease outbreaks, emerging infectious diseases, and MDROs; new and proposed mandatory reporting requirements; and the release of evidence-based practices for preventing infections. They also provide Internet links for obtaining more information, including prevention and control measures. Refer to the Resources section at the end of this chapter for additional information.

IPs can also use a variety of social media to obtain and share information related to surveillance activities.

### *AUTOMATED OR ELECTRONIC SURVEILLANCE*

Automated surveillance can be defined as the process of obtaining useful information from infection prevention data "through the systematic application of medical informatics and computer science technologies."<sup>59</sup> Because manual methods for obtaining and evaluating the data needed to identify HAIs are time consuming, error prone, and labor intensive, data should be collected, managed, and analyzed using information technology whenever possible.<sup>60,61,62</sup>

Automated surveillance programs that use existing electronic clinical, laboratory, pharmacy, and other health data can improve the sensitivity, accuracy, and objectivity of surveillance and decrease the burden of data collection.<sup>59,63,64,65,66</sup> A variety of automated systems exist, including programs developed internally by a healthcare organization and those available commercially.<sup>60,63,66</sup> CDC **TAP reports** described earlier in this chapter are an example of an electronic reporting system based on data collected for NHSN.

APIC has a position paper that discusses and supports the use of automated surveillance technologies.<sup>60</sup> APIC provides related information that can be accessed by entering the key words "surveillance technology" into the search function on the APIC home page ([www.apic.org](http://www.apic.org)).

## BENCHMARKING AND COMPARING DATA

Benchmarking is the process of comparing oneself to others that are performing similar activities for the purpose of improving performance. Although it is very appealing to compare one's rates externally with those of others, comparisons should be made only after ensuring that the following conditions are met:<sup>23,67</sup>

- Criteria for defining a case are standardized and up-to-date
- Criteria are consistently used by all participants and all data collectors
- The population and time period for study are well defined
- The data collection and surveillance methodology are standardized and consistently used by all participants over time
- Rates and ratios are calculated using the same numerators (number of cases) and denominators (e.g., population at risk, device-days, patient-days)

- The size of the population studied (denominator) is large enough to provide an accurate estimate of the true rate
- A standardized risk adjustment method is used by all participants
- All data collectors receive training on how to collect data and use a standardized form
- The facility and population being compared are similar to the types of facilities and populations in an aggregate database used for external comparison (e.g., data from a neonatal ICU is compared with data aggregated from other neonatal ICUs)
- The aggregating organization has a mechanism for ensuring the accuracy, sensitivity, and specificity of the data submitted
- The reports, analysis, and interpretation of the data provided by the benchmarking system are accurate and in a form that is understandable to the users
- Feedback will be disseminated to those who can effect change
- The data provided by an organization to an external aggregating system are coded for confidentiality, and the reports provided to the organization or to others do not contain facility identifiers unless the data are being used for a public reporting program

### *BENCHMARKING AND COMPARATIVE DATABASE SYSTEMS WORLDWIDE*

Benchmarks are measures against which outcomes and processes can be compared. There are currently few validated external benchmarks that can be used for interfacility comparisons of HAIs and other adverse events. Worldwide, efforts are under way to standardize infection surveillance criteria and methodology. Additional work is needed to identify useful methods to risk adjust populations studied, and to develop information technology to improve the ability to collect, manage, and report data and compare populations for benchmarking and performance improvement. <sup>68,69,70</sup>

In the United States, efforts have been made to establish systems for benchmarking in a variety of settings: acute care, <sup>25</sup>,<sup>67</sup> hemodialysis, <sup>47,48</sup> LTC, <sup>38,39,40</sup> home care, <sup>55,56</sup>,<sup>81</sup> and ambulatory surgery.

<sup>46</sup> The NHSN, discussed below, is the oldest and most widely used comparative database used in the United States for HAIs.

### *COMPARING RATES*

Statistical methods should be used to compare differences between populations studied. For example, if a hospital uses NHSN methodology to collect and analyze surgical site infection data, then it can use the z-test and standardized infection ratio (SIR) to compare its risk-adjusted SSI rates with the rates in the NHSN System Reports.<sup>82,83</sup> The use of z-tests and the SIR to compare rates between two defined populations is discussed elsewhere in this text. Other statistical methods that are used to compare differences between populations, such as the t-test, chi-square test, Fisher's exact test, confidence intervals, and the 2 &times; 2 table, are also discussed elsewhere in this text. **TAP Reports** which include CAD metrics that allow facilities to compare internal unit infection rates and to compare rates across timeframes.

## IMPROVING PERFORMANCE, PATIENT SAFETY, AND INFECTION PREVENTION

One of the main purposes for conducting surveillance is to provide information that can be used to target performance improvement activities.<sup>1</sup>,<sup>26,67</sup> There are many published reports that demonstrate

the use of surveillance data to identify potential problems and risk factors for infection, implement prevention and control measures, and document the reduction of infection rates in a variety of healthcare settings.<sup>6,67,67</sup> An effective infection prevention and control program incorporates a surveillance program that enhances a healthcare organization's performance improvement activities and reduces the risk of adverse outcomes.<sup>26</sup>

Critical elements that have been shown to be successful in reducing infection rates include the following:<sup>67</sup>

- Voluntary participation and confidentiality
- Standard definitions and protocols
- Defined populations at risk (e.g., intensive care, surgical patients)
- Site-specific, risk-adjusted infection rates comparable across institutions
- Adequate numbers of trained IPs
- Dissemination of data to healthcare providers
- A link between monitored rates and prevention efforts<sup>16</sup>

Since the release of the Institute of Medicine report on patient safety and medical errors in 1999, infection prevention and performance improvement communities have focused their attention on the role of infection prevention in providing a safe healthcare environment.<sup>16</sup> Infection prevention is a critical component of patient safety.<sup>16</sup> Infection prevention and patient safety activities can complement and benefit each other. For example, patient safety practices, such as continuous quality improvement and root cause analysis, can augment infection prevention and control programs.<sup>89</sup> Root cause analysis can be used to review HAIs that are implicated as attributable causes of death.<sup>86,89,96</sup> Conversely, traditional infection prevention practices that can benefit the patient safety field include the use of trained professionals and "valid definitions of infection-related adverse events, standardized methods for detecting and reporting events, confidentiality protections, appropriate rate adjustments for institutional and case-mix differences, and evidence-based intervention programs."<sup>89</sup>

## THE NATIONAL HEALTHCARE SAFETY NETWORK

In 2005, the CDC integrated three of its patient and healthcare worker surveillance systems into the NHSN as follows:

- NHSN, which replaced the National Nosocomial Infections Surveillance System for HAI surveillance in acute care hospitals, monitors HAIs and other healthcare events (e.g., blood safety errors and healthcare process measures such as adherence to central line insertion practices and antimicrobial use).<sup>25,97</sup>
- National Surveillance System for Health Care Workers, which monitors healthcare personnel immunization, tuberculin skin testing programs, and exposures to blood and body fluids, vaccine preventable diseases, and tuberculosis.<sup>97</sup>
- Dialysis Surveillance Network, which is a national surveillance system that monitors bloodstream and vascular infections in adult and pediatric patients treated in outpatient hemodialysis centers.<sup>48,49</sup>

The NHSN provides a Web-based reporting and knowledge system for patient and healthcare personnel safety information, feedback of comparative data for performance improvement, and access to prevention tools and best practices. NHSN monitors infection-related events that include CLABSIs, CAUTIs, SSIs, ventilator-associated events, and *C. difficile* and other drug-resistant infections. The NHSN

website ([49](#)) provides protocols, data collection forms, training, case studies, supporting materials, and analysis resources.

As of December 2012, close to 30 states use NHSN for state-specific HAI reporting mandates.[34](#)Hospitals participating in the CMS Hospital Inpatient Quality Reporting Program are required to report HAI data to NHSN. Consequently, as of August 2013, more than 11,000 facilities use NHSN.[34](#)These facilities include acute care hospitals, long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and nursing homes. Hospitals and dialysis facilities comprise the majority of participating facilities, although the number of facility types is increasing.

## DETECTION OF HEALTHCARE-ASSOCIATED OUTBREAKS

Only a small proportion of HAIs are related to an outbreak.[8,67,101](#)In the healthcare setting, most outbreaks are suspected when routine surveillance activities detect a cluster of cases, an unusual organism, or an apparent increase in the occurrence of an organism or event; a clinician diagnoses an unusual disease; or a healthcare provider or laboratory worker notices a cluster of cases. Data mining and electronic or automated surveillance programs can be used to detect potential outbreaks of infection.[102,103](#)

## SURVEILLANCE FOR INFECTIONS ASSOCIATED WITH THE HEALTHCARE ENVIRONMENT

### *SURVEILLANCE OF PATIENTS AND RESIDENTS*

Ensure that the surveillance program monitors patients and residents for infections that are associated with the healthcare environment. Refer to published guidelines for the surveillance, prevention, and control of diseases associated with the environment, such as aspergillosis and legionellosis.[104,105](#)

### *ENVIRONMENTAL SAMPLING*

Guidelines for environmental sampling (i.e., culturing) of the environment, including air, water, and environmental surfaces, have been published by the CDC and others.[104,105](#)Routine or random, undirected microbiological culturing of air, water, and environmental surfaces in healthcare facilities is not recommended.[104](#)Culturing is indicated, however, for selected quality assurance purposes, such as biological monitoring of sterilizers using bacterial spores and cultures of water and dialysate in hemodialysis units.[104,106,107](#)

Cultures of environmental sources may be indicated as part of an outbreak investigation if epidemiological data implicate an environmental source and results can be used to direct infection prevention decisions.[104](#)Environmental sampling should be conducted only under the guidance of a multidisciplinary team and in accordance with written protocols that define sample collection and culturing methods, how to interpret results, and what actions will be taken on the basis of the findings.[104](#)

In the past decade, studies have implicated environmental and medical device surfaces in the transmission of pathogens and subsequent colonization and infection of patients. Pathogens that have been linked to transmission via contaminated environmental surfaces and medical equipment include MRSA, VRE, *C. difficile*, *Pseudomonas aeruginosa*, *Acinetobacter* spp., and norovirus.[108](#)This has led to an increased focus on cleaning and disinfection of these surfaces. In addition to surveillance for the occurrence of these organisms, many healthcare facilities conduct process surveillance to monitor



cleaning and disinfection protocols. Some facilities use tools such as adenosine triphosphate (ATP) or fluorescent gel or powder as a surrogate for surveillance cultures.<sup>[109](#)</sup>

## SURVEILLANCE FOR PUBLIC HEALTH, EMERGING INFECTIOUS DISEASES, AND BIOTERRORISM

Surveillance is the key to recognizing outbreaks and new or emerging infectious diseases so that control measures can be instituted to contain their spread. Disease surveillance in the United States is based on a passive system in which healthcare providers and laboratories report unusual or reportable conditions to a public health department. Therefore, IPs and healthcare personnel play an integral role in detecting and reporting diseases of public health significance.

Community outbreaks have been recognized after IPs and other healthcare personnel reported disease cases to the local health department.<sup>[110](#)</sup>A bioterrorist event associated with the release of anthrax spores was first detected when an astute clinician reported a case of inhalational anthrax.<sup>[111](#)</sup>In the past two decades, healthcare providers have been instrumental in detecting and reporting emerging infectious diseases, such as hantavirus pulmonary syndrome, gastroenteritis caused by norovirus, hemolytic uremic syndrome due to *Escherichia coli* O157:H7, severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome coronavirus (MERS-CoV).<sup>[111](#)</sup>Community outbreaks, such as influenza, RSV, and SARS have affected healthcare personnel, patients, and residents of healthcare institutions and can disrupt and overwhelm healthcare services.<sup>[113](#)</sup>

IPs should subscribe to email alerts and other warning systems that can be used to monitor the occurrence of local, state, national, and international outbreaks and recommendations for response. Examples are provided in the Resource section at the end of this chapter.

The Institute of Medicine and the CDC have published recommendations for addressing the threat of emerging infectious diseases and bioterrorism that include strengthening disease surveillance systems.<sup>[113](#),[114](#),[116](#),[117](#)</sup>Syndromic surveillance has been used to detect potential bioterrorist events and respiratory syndromes.<sup>[117](#)</sup>Advances in health information technology have prompted the CDC and CMS to investigate the use of current syndromic surveillance practice beyond the emergency and urgent care settings.<sup>[121](#)</sup>Many guidelines have been published for bioterrorism and pandemic response and planning, and these are discussed elsewhere in this text.

There is no doubt about the interdependence of infection prevention, clinical medicine, and public health.<sup>[118](#)</sup>Individuals who are responsible for managing surveillance programs in healthcare settings should ensure that sufficient resources are allocated for the surveillance of diseases of public health significance, including reportable conditions, emerging infectious diseases, and infections associated with bioterrorism.

## SURVEILLANCE FOR MULTIDRUG-RESISTANT ORGANISMS

Antimicrobial resistance has been increasing in both healthcare-associated and community-acquired infections worldwide, and vancomycin resistance in *S. aureus* has been detected.<sup>[118](#)</sup>Surveillance to detect MDROs has been advocated for decades, and a healthcare organization's surveillance program should monitor microbiology reports for the occurrence of resistant organisms of epidemiological importance to the facility.<sup>[125](#)</sup>

Surveillance cultures and other microbiologic tests, such as molecular rapid antigen detection tests, can also be done to monitor the incidence, prevalence, and transmission of MDROs. Once used primarily in outbreak investigations, the use of active surveillance testing (AST) has been recommended to identify

colonization of patients and residents with MDROs in select populations in nonoutbreak situations.<sup>[122](#),[122](#)</sup>The use and efficacy of AST for MRSA and other MDROs in nonoutbreak situations have been widely debated.<sup>[129](#)</sup>However, AST has been shown to reduce the incidence of MRSA when used in defined populations in conjunction with strict adherence to other infection prevention measures, such as isolation precautions and hand hygiene.<sup>[130](#)</sup>Some state agencies require AST for MRSA and other MDROs, and IPs must ensure that their organization complies with these requirements.<sup>[131](#)</sup>The use of AST is discussed in more detail elsewhere in this text.

## MANDATORY AND PUBLIC REPORTING

Mandatory and public reporting initiatives significantly affect surveillance activities in healthcare organizations and have caused technical and resource challenges.<sup>[131](#)</sup>Since 2002, at least 35 states and Washington, DC, have enacted legislation and other mandates that require healthcare facilities to report data on HAIs, epidemiologically significant organisms such as MRSA, and related quality measures (e.g., the Surgical Care Improvement Project indicators, healthcare personnel influenza immunization, and hand hygiene compliance).<sup>[8](#),[134](#)</sup>Information about specific reporting requirements for each state can be obtained from individual state quality measurement agencies and health departments and the Public Policy section of the APIC website at [134](#).

In addition to state mandates, since 2002 CMS has been phasing in public reporting, pay-for-performance, and value-based purchasing initiatives for healthcare providers. Affected healthcare settings include nursing homes, acute care hospitals, long-term acute care, outpatient dialysis, inpatient rehabilitation, and ambulatory surgery centers. Among other requirements, beginning in 2011, CMS has been introducing mandatory reporting of a variety of HAI events via the NHSN. Information on CMS requirements for NHSN submission is available on the CDC website at <http://www.cdc.gov/nhsn/cms/>.

The primary goal of public reporting is to increase the quality of healthcare processes and outcomes. IPs must ensure that their organization accurately collects and submits the HAI-related data required by state and federal agencies. The IP should then assist their organization assess the findings in the reports released by those agencies and utilize them in its performance improvement activities.

## New Developments

In the past decade, developments affecting surveillance programs in healthcare settings include:

- A continuing shift from acute inpatient care to ambulatory and LTC services<sup>[7](#)</sup>
- Decreased length of stay across the continuum of care<sup>[7](#)</sup>
- Expanding requirements for public and mandatory reporting of data relating to HAIs<sup>[9](#),[69](#),[132](#),[133](#)</sup>
- The successful use of surveillance data to focus performance improvement activities and to demonstrate reduced infection rates and increased compliance with infection prevention practices<sup>[133](#),[67](#)</sup>
- An emphasis on the use of benchmarking and statistical methods to compare infection rates between groups<sup>[47](#),[48](#),[48](#)</sup>
- A culture change that promotes infection *prevention*, rather than infection control, aims for zero HAIs<sup>[135](#)</sup>



- Emerging and reemerging infectious diseases and organisms, such as SARS, hantavirus pulmonary syndrome, avian influenza, MERS-CoV, norovirus, multidrug-resistant *Acinetobacter baumannii*, and highly virulent strains of *C. difficile*
- The threat of bioterrorism and the use of syndrome surveillance<sup>[111](#),[111](#)</sup>
- The application of information technology, including data mining and automated surveillance systems, to lessen the burden of data collection, identify HAIs, comply with HAI reporting mandates, and affect performance improvement activities<sup>[54](#),[102](#),[136](#)</sup>
- The effective use of surveillance data to monitor noninfectious events, such as sharps injuries and compliance with infection prevention protocols (e.g., hand hygiene and healthcare personnel influenza immunization), and to improve healthcare practices<sup>[136](#)</sup>
- Renewed focus on the role of the healthcare environment in the transmission of infectious agents and the need for surveillance for these agents<sup>[108](#),[109](#)</sup>
- The use of AST of patients and residents to detect MDROs so that additional infection prevention measures can be instituted to limit their spread<sup>[122](#),[122](#)</sup>
- The use of information technology to rapidly transfer information on the occurrence of outbreaks, emerging infectious diseases, and infection prevention measures
- CMS initiatives to implement pay-for-performance, value-based purchasing, and public reporting programs<sup>[122](#)</sup>

## Conclusions

Surveillance methodology evolves in response to changes in the healthcare delivery system, the use of surveillance data, and diseases prevalent in the populations served. In the past decade, healthcare delivery has continued to shift outside of the traditional acute care hospital, resulting in a growing need for surveillance in other healthcare settings. The use of surveillance data has shifted from merely measuring clinical outcomes, such as infections, to guiding performance improvement activities and demonstrating improvements in both clinical outcomes and healthcare practices. The increasing occurrence of antimicrobial resistance worldwide, outbreaks caused by emerging and reemerging infectious diseases, and the threat of bioterrorism has highlighted the need for local, regional, national, and global surveillance systems. IPs and others who are responsible for implementing and managing surveillance programs in healthcare settings must ensure that their programs are based on sound epidemiological and statistical principles, are designed and evaluated in accordance with current recommendations and practices, and have the resources needed to promote quality healthcare.

## Future Trends

Future trends that will affect surveillance programs in healthcare settings include:

- More widespread implementation of post-discharge surveillance to monitor HAIs, especially SSIs, that develop after discharge<sup>[140](#)</sup>
- The growth of national and global surveillance systems to detect antimicrobial resistance, bioterrorist events, naturally occurring epidemics, and emerging infectious diseases<sup>[140](#)</sup>
- Expanding requirements for public and mandatory reporting of data relating to HAIs

- Expanding use of data related to HAIs as quality indicators in pay-for-performance, value-based purchasing, and public reporting programs by CMS and others
- Increased pressure from patients, government agencies, healthcare insurers, quality improvement organizations, healthcare providers, IPs, the media, and others for healthcare organizations to aim to eliminate HAIs
- Expanded use of electronic surveillance and information technology to identify HAIs and reduce the burden of collecting, managing, and analyzing data
- The use of information technology to rapidly transfer information on disease occurrence and infection prevention methods
- Increased coordination of disease surveillance activities among the infection prevention, academic, clinical, and public health communities
- Use of syndromic surveillance beyond the emergency and urgent care settings

Further research is needed to:

- Enable the development of quantitative, objective, surveillance definitions to identify HAIs, facilitate automation, improve comparability, and minimize gaming<sup>[140](#)</sup>
- Identify effective methods for standardizing the processes for collecting, managing, and reporting surveillance data so that data can be accurately compared between organizations<sup>[147,148](#)</sup>
- Advance the use of information technology in surveillance for HAIs and public health<sup>[148](#)</sup>
- Evaluate the effect of public reporting of healthcare quality data on the processes and outcomes of care<sup>[153,154](#)</sup>

## International Perspective

### SURVEILLANCE FOR HEALTHCARE-ASSOCIATED INFECTIONS

National surveillance programs for HAIs exist in many countries. As in the United States, infection prevention and infectious disease professionals in these countries are endeavoring to standardize infection surveillance criteria and methodology; develop risk stratification methods; improve information technology to collect, manage, and analyze data; and develop benchmarking and comparative database systems.<sup>[70,70,155](#)</sup>

### SURVEILLANCE FOR ANTIBIOTIC-RESISTANT ORGANISMS

MDROs are well recognized worldwide, and many countries have surveillance and control programs to identify their occurrence and limit their spread. However, many nations do not have surveillance or control programs, and global surveillance systems are needed to rapidly detect MDROs and institute measures to prevent further transmission.<sup>[156](#)</sup>

### SURVEILLANCE FOR OUTBREAKS AND EMERGING INFECTIOUS DISEASES

In 2000, the World Health Organization organized the development of the Global Outbreak Alert and Response Network (see website at <http://www.who.int/csr/outbreaknetwork/en/>). This is a network of existing institutions and networks that pool resources for the rapid identification, confirmation, and response to outbreaks of international importance. The global outbreak of SARS in 2003 highlighted the need for worldwide surveillance networks.<sup>[141](#)</sup> The rapid transmission of SARS emphasized the value of collaboration among the international infection prevention, clinical, and public health communities to

rapidly detect cases, transfer information, and identify and implement measures to control the spread of the disease.**157**

## Supplemental Resources

### PUBLICATIONS

Centers for Disease Control and Prevention (CDC). Self-Study Course SS1978. *Principles of Epidemiology in Public Health Practice: An Introduction to Applied Epidemiology and Biostatistics*, 3rd ed. CDC website. 2011. Available at: [http://www.cdc.gov/osels/scientific\\_edu/ss1978/](http://www.cdc.gov/osels/scientific_edu/ss1978/).

*Emerging Infectious Diseases*Journal (published electronically by the CDC). Available at: <http://www.cdc.gov/ncidod/EID/index.htm>.

Greene LR, Cain TA, Khoury R, et al. APIC position paper: the importance of surveillance technologies in the prevention of health care-associated infections. *Am J Infect Control*2009 Aug;37(6):510–513.

*Morbidity and Mortality Weekly Report*(MMWR), *MMWR Recommendations and Reports*, *MMWR Surveillance Summaries* and *MMWR Supplements*(published electronically by the CDC). Available at: <http://www.cdc.gov/mmwr/>.

### WEBSITES

APIC (<http://www.apic.org>)

- Legislative map: Available at: <http://www.apic.org/Advocacy/Legislation>.
- Public policy resources: Available at: <http://apic.org/Advocacy/Government-Affairs-Resources>.
- Application of Information Systems for Infection Prevention & Control: A Select Bibliographic Compendium. Wright MO, Olmsted RN. June 2010 at [http://www.apic.org/Resource\\_/TinyMceFileManager/Practice\\_Guidance/Surveillance-technology-literature-references.pdf](http://www.apic.org/Resource_/TinyMceFileManager/Practice_Guidance/Surveillance-technology-literature-references.pdf).

Centers for Disease Control and Prevention (CDC) (<http://www.cdc.gov>)

- Healthcare-associated infections: Available at: <http://www.cdc.gov/hai>.
- National Healthcare Safety Network (NHSN) home page: Available at: <http://www.cdc.gov/nhsn>.

Center for Infectious Disease Research and Policy (CIDRAP) (<http://www.cidrap.umn.edu/>)

- Sign up for newsletters for News and perspectives on outbreaks.

Centers for Medicare & Medicaid Services (CMS) (<http://www.cms.gov>)

- Quality Initiatives: Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html>.
- Hospital Acquired Conditions (Present on Admission Indicator): Available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond>.

World Health Organization (<http://www.who.int>)

- Global Outbreak Alert and Response Network: Available at:  
<http://www.who.int/csr/outbreaknetwork/en>.
- Core components for infection prevention and control programmes: Assessment tools for IPC programmes. WHO/HSE/GAR/BDP/2011.3. Available at:  
[http://www.who.int/csr/resources/publications/HSE\\_GAR\\_BDP\\_2011\\_3/en](http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2011_3/en).

## ORGANIZATIONS PROVIDING COMPARATIVE DATABASES FOR INFECTION SURVEILLANCE

These examples are for information only; citation does not imply endorsement by APIC.

CDC NHSN: Available at: <http://www.cdc.gov/nhsn>.

Missouri Alliance for Home Care (MAHC) Infection Surveillance Project: Available at:  
<http://www.homecaremissouri.org/projects/infection/index.php>.

International Quality Indicator Project: Available at: <http://www.internationalqip.com>.

Vermont Oxford Network: Available at: <http://www.vtoxford.org>.

## RESOURCES FOR STATISTICAL MEASUREMENT

The *StatPages.net Website* contains Web pages that perform statistical calculations: Available at:  
<http://statpages.org>.

The Epi Info software program—created by the Epidemiology Program Office of the CDC. Epi Info is a public domain package that provides for easy form and database construction, data entry, and analysis with epidemiological statistics, maps, and graphs. Available at: <http://www.cdc.gov/epiinfo>.

## ELECTRONIC NOTIFICATION SYSTEMS

CDC Clinician Outreach Communication Activity (COCA). Communication network developed to provide two-way communication between clinicians and the CDC about emerging health threats, such as pandemics, natural disasters, and terrorism. Subscribe at: <http://emergency.cdc.gov/coca/about.asp>.

CDC Health Alert Network (HAN). CDC's primary method of sharing cleared information via email about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories. Subscribe at:  
<http://emergency.cdc.gov/HAN/>.

FDA MedWatch. MedWatch distributes alerts on contaminated medical products, such as intravenous solutions, and suspected outbreaks associated with medical devices and products via the MedWatch E-list. Subscribe at: <http://www.fda.gov/medwatch/elist.htm>.

ProMED-mail. ProMED-mail (the Program for Monitoring Emerging Diseases) is a program of the International Society for Infectious Diseases. A team of moderators posts reports to ProMED from various sources, including public health agencies, the media, local observers, and ProMED-mail subscribers. The ProMED program provides a platform for discussion, requests for information, and collaboration in outbreak investigations and prevention efforts. Subscribe at:  
<http://www.promedmail.org>.

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## Outbreak Investigations

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### Abstract

*Outbreaks of both infectious and noninfectious adverse events can occur in any healthcare setting and pose a threat to patient safety. Regardless of scope, investigation of a potential outbreak involves certain epidemiological components. Cooperation between healthcare epidemiologists, infection preventionists, and public health experts is important in effectively managing outbreak responses in healthcare settings. The ultimate goal of any outbreak investigation is to identify probable contributing factors and to stop or reduce the risk for future occurrences.*

### Key Concepts

- Outbreaks should be suspected when healthcare-associated infections, recovery of specific pathogens, or other adverse events occur above the background rate or when an unusual microbe or adverse event is recognized.
- Outbreaks in healthcare settings may be due to a variety of factors, including lapses in infection prevention or clinical practices, contaminated or defective products or devices, and colonized or infected healthcare personnel.
- Outbreaks in healthcare are often multifactorial.
- Epidemiological investigations of a possible outbreak must be conducted in a standardized way that assesses the possible contributing factors.
- Ending an outbreak involves modifying one or more of the contributing factors.
- The goals of an outbreak investigation are to identify contributing factors to control the outbreak and prevent similar outbreaks in the future.

## Background

Outbreaks in healthcare should be suspected when healthcare-associated infections (HAIs) or adverse events occur above the background rate or when an unusual microbe or adverse event is recognized. They can occur in any healthcare setting, and it is important to remember that the onset of symptoms for patients involved in a healthcare-associated outbreak may occur after the patient has left the facility, especially in outbreaks occurring in outpatient settings. Healthcare-associated outbreaks often have multiple causes, but almost all are due to one or more of the following: lapses in infection prevention or clinical practices, colonization or infection of healthcare personnel (HCP), or defects in or contamination of a product or device, either at the time of production (intrinsic contamination) or during use (extrinsic contamination). Outbreaks in healthcare settings may also be caused by visitors who have, or are harboring, an infectious disease (e.g., influenza or chickenpox).

As healthcare delivery moves increasingly to noninpatient settings, outbreaks are increasingly being recognized in outpatient facilities. Because these facilities often lack the healthcare epidemiology and infection prevention infrastructure present in inpatient, acute care hospitals and because the adverse events generally occur after the patient has left the facility, the detection, investigation, and control of outbreaks in outpatient settings is especially challenging. Likewise, the rapid introduction of new technologies has increased the number of potential causes of HAI outbreaks and has led to the recognition of items such as tissue allografts and compounded pharmaceutical products as outbreak sources.

Epidemiological investigations of outbreaks should be conducted in a standardized way. Areas that must be assessed include the source(s), the pathogen(s), the host(s), and the mode(s) of transmission. Factors associated with these areas contribute to the development of the outbreak, and modification of one or more of these factors will end the outbreak. The goal of any outbreak investigation is to control the outbreak by identifying and modifying contributing factors and to develop and implement measures to prevent similar outbreaks in the future. This chapter assists healthcare epidemiologists and infection preventionists in determining when a situation should be investigated and how to conduct an investigation.

## Basic Principles

### OUTBREAK INVESTIGATION

#### *RECOGNITION OF A POTENTIAL OUTBREAK*

Epidemics or outbreaks are defined as an increase over the expected occurrence of an event. Given that definition, it is important to note that a single case of an unusual disease (e.g., postsurgical group A streptococcus infection, healthcare-associated *Legionella* infection) may constitute an outbreak. In some instances, small outbreaks are referred to as “clusters,” but both outbreaks and clusters require prompt investigation. The term “pseudo-outbreak” is generally applied to situations in which there is a rise in test results (e.g., positive microbiology cultures) without actual clinical disease.

Surveillance for HAIs and adverse events can be a great aid in the recognition of outbreaks in healthcare settings because it provides both a baseline rate and ongoing monitoring. However, because outbreaks often occur in areas that are not under surveillance, most healthcare-associated outbreaks are recognized by observant HCP and infection preventionists.

Although local and state health department requirements may differ, most require reporting of possible healthcare-associated outbreaks as soon as they are suspected. Public health officials may also be able to assist in arranging or providing epidemiological and/or laboratory support. When a contaminated or defective product (including blood and human tissues), device, or medication is suspected as the cause of an outbreak, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) should be notified.

### *CONDUCTING AN OUTBREAK INVESTIGATION*

Although outbreaks are generally divided into steps for the purposes of teaching and explanation, it is important to remember that outbreaks generally do not unfold in a linear or orderly manner. Thus, it is possible that not all of the steps described in the following discussion will be applicable in all settings and it is possible, if not likely, that many steps might have to occur simultaneously and be repeated multiple times in the course of the investigation. In general, outbreak investigations can be divided into two major sections, the initial investigation and the follow-up investigation, each with multiple components.

The primary components of the initial investigation include the following:

- Confirming the presence of an outbreak
- Alerting key partners about the investigation
- Performing a literature review
- Establishing a preliminary case definition
- Developing a methodology for case finding
- Preparing an initial line list and epidemic curve
- Observing and reviewing potentially implicated patient care activities
- Considering whether environmental sampling should be performed
- Implementing initial control measures

The primary components of the follow-up investigation include the following:

- Refining the case definition
- Continuing case finding and surveillance
- Reviewing regularly control measures
- Considering whether an analytic study should be performed

### **Components of Initial Outbreak Investigations**

#### *Confirming Presence of an Outbreak*

Outbreaks are defined simply as an increase over the expected occurrence of an event. When a possible outbreak is reported, the initial step in the investigation is to confirm that what is being reported indeed represents an increase in the outcome. For infectious disease outbreaks, this might be done by reviewing surveillance or microbiology records. For outbreaks of other adverse events, historic, comparative data might be more difficult to obtain. In these instances, the decision to initiate an outbreak investigation might be based on the general perception of clinicians about whether or not the current occurrence of the event exceeds the baseline.

### *Alerting Key Partners About the Investigation*

At the outset of an outbreak investigation, it is critical to inform key partners of the situation. Facility administration should be notified so that resources can be made available and so that risk management and public affairs staff can prepare to assist. The microbiology laboratory should be notified and asked to alert the infection preventionists or the infection prevention or epidemiology department of new possible cases and to save any isolates that might be related to the outbreak.<sup>1,2</sup> Finally, as mentioned previously, local, and, as appropriate, state and federal public health officials should be notified.

### *Performing a Literature Review*

There are many reports summarizing outbreak investigations published in the literature, and hence a literature review is a critical early step in any investigation. The literature review will help identify possible sources that might merit further investigation and might also provide important insight into optimal investigative methodology. An excellent pathway for a literature review includes the National Library of Medicine (available at <http://www.nlm.nih.gov/>). The CDC (available at [www.cdc.gov/](http://www.cdc.gov/)) provides an abundance of information ranging from current outbreaks and immunizations to disease-specific subject matter. An instrumental reference tool for infection prevention and control measures can be found in the *Control of Communicable Disease in Man*, 19th edition.<sup>3</sup>

### *Establishing an Initial Case Definition*

Develop specific criteria for the definition of a case. The initial case definition should be narrow enough to focus investigative efforts but broad enough to capture the majority of cases. In outbreaks of infectious diseases, the decision on how broad to make the case definition is often driven by the pathogen. Outbreaks of rare pathogens may allow for broader definitions (e.g., any case where *Ralstonia* species were recovered), whereas those caused by more common pathogens will require more stipulations (e.g., *Staphylococcus aureus* surgical site infections [SSIs] following cardiac surgery). In outbreaks of infections, careful consideration should be given to whether or not the case definition should have a microbiologic component. On one hand, requiring that cases have a culture for a specific organism is often quite helpful in both focusing the investigation and facilitating case finding. However, in some instances, this requirement might also miss cases. Decisions about requiring a microbiologic confirmation of cases often depends on the pathogen. For example, influenza-like illness might be preferred to confirmed influenza, and on the clinical syndrome, for example, SSIs might be preferred to SSIs due to a specific pathogen at least in the initial stages of an investigation.

### *Developing a Methodology for Case Finding*

A variety of sources can be used to find additional cases that might be related to the outbreak. If the case definition includes a laboratory result, laboratory records are a logical place to start and can facilitate rapid identification of possible cases. If the outbreak involves an HAI or adverse event or a multidrug-resistant pathogen for which the facility is performing surveillance, infection prevention and surveillance records can be useful for case finding. Finally, discussions with HCP in affected areas can also be helpful in identifying possible cases, particularly in outbreaks in which the case definition is primarily clinical.

Another issue to consider in outbreaks of many healthcare pathogens is whether or not there might be additional patients who are colonized with only the outbreak pathogen. In those cases, examining only clinical culture results might underestimate case-finding efforts and could compromise control efforts if the colonized patients continue to serve as a reservoir for transmission. In these instances, surveillance

cultures might be needed to identify additional cases. However, the benefits of performing surveillance cultures must be weighed against the resources required. One option that can be useful is the performance of a single round of surveillance cultures, sometimes referred to as a “point prevalence” survey, which can help assess the scope of the problem and determine whether ongoing surveillance cultures will be needed.

### *Preparing an Initial Line List and Epidemic Curve*

The line list is, perhaps, the single most important tool in any outbreak investigation, and hence merits considerable early discussion and effort. In general, information that can be helpful on a line list can include details about patient signs or symptoms (if there is the possibility that it is a pseudo-outbreak), medications, procedures, consults, patient locations, contact with HCP, and host factors that might have predisposed the patients to the adverse event under investigation. Although they are powerful tools in guiding investigations, developing line lists is a resource-intensive activity because it involves a review of a variety of different sources of information, which might include medical records, patient location information (admission, discharge, and transfer data), and staff interviews. Thus, it is critical to carefully weigh the benefits of any information to be included on the line list against the resources required to obtain it. One option is to create an initial simple line list with some very basic information on potential exposures, such as invasive procedures and hospital locations. This type of limited line list can be useful in helping focus subsequent investigative efforts if many of the patients do have a common exposure. However, it is important to remember that these preliminary line lists can sometimes be misleading because not every case patient may have been exposed to the common source and some exposures might be associated with only cases and not the actual source of the outbreak. As with any part of an outbreak investigation, it is important to continue to reassess the information on the line list in the context of all of the other information being gathered.

Data from the line list should also be used to create an epidemic curve (see Chapter 10 General Principles of Epidemiology). In some instances, the shape of the epidemic curve will provide information that can help identify the mode of transmission. However, there are important caveats to interpreting epidemic curves in healthcare-associated outbreaks. First, patients may become colonized with organisms well before they develop clinical infections and some patients will not develop infections at all. Hence, the “incubation period” suggested by the line list is often misleading for many healthcare pathogens. Second, exposures in healthcare settings are often ongoing and organisms may be transmitted from patient to patient, in addition to coming from a common, contaminated source. Hence, the shape of the curve in a “point-source” healthcare-associated outbreak might look very different from that seen in a point-source outbreak of a foodborne disease.

### *Observing and Reviewing Potentially Implicated Patient Care Activities*

In most outbreak investigations, it is the observations of practices that ultimately identify the cause. The line list is critical in helping guide both the type and location of observations that will need to be done. For infectious disease outbreaks, the type of pathogen and infection being investigated can also be important factors. For example, investigations of outbreaks of *Aspergillus* should generally include careful review and observations of construction activities in or near patient areas. Initial observations should generally be free-form, that is, without a detailed observation form and should focus on practice patterns and workflow that deviate from good infection prevention practices and facility or unit policies. More detailed and focused observations tools can be developed if needed but should be informed by the free-form observations. It is also very helpful to pay careful attention to how practices might differ among HCP. During these observations, it is important to engage HCP in a discussion about the outbreak being investigated and the potential contributing factors. It is vital that the HCP understand that the

investigation is collaboration between them and healthcare epidemiology, not an attempt to assign blame. Some important questions to ask that might lead to key insights include the following:

- Do you always do this procedure in the way I observed? Are there situations that might require that you do it differently?
- Have you seen other people do it differently?
- What are the challenges with maintaining good techniques?
- What do you think is causing or contributing to the outbreak?
- What procedures or medications might I be missing because they are not in the chart or are done infrequently?

In addition to specific practices, observations should also review adherence to general infection prevention practices such as hand hygiene and compliance with transmission-based precautions. In addition to helping delineate the potential causes of outbreaks, these observations can also provide useful “teachable moments” in infection prevention and control.

### *Considering Whether Environmental Sampling Should Be Performed*

In outbreaks of infectious diseases, identifying a contaminated source is often one of the most satisfying and definitive investigative findings. However, environmental culturing during outbreak investigations can also be the most frustrating, expensive, and potentially misleading aspect of an investigation. More often than not, these cultures are negative and leave the investigator to ask why. Was it because the item cultured is actually not the source of the outbreak, or because the implicated organism was there before, but was not there when the culture was obtained? Or perhaps because the wrong part of the item was sampled? Or because the technique used was not sensitive enough to detect the contamination? There are also important methodological challenges in both obtaining and processing environmental samples. For example, culture swabs used in many facilities to sample surfaces can be used on only small surface areas. Also, some environmental pathogens, particularly waterborne agents, have adapted to survive in very-low-nutrient settings and require special media to grow in the microbiology laboratory. Finally, the yield of surface cultures may be limited by residual disinfectants that must be neutralized before the sample is processed.

Given these challenges, some important recommendations can improve the yield of environmental cultures as follows:

- Perform these cultures after making the line list and doing observations so that they can focus on items that seem the most likely to be implicated. Environmental cultures should never be the first step in an outbreak investigation.
- Before obtaining any environmental cultures, talk with microbiology laboratory personnel to determine whether they are able to process the cultures that will be obtained and discuss the optimal methods of obtaining them.
- Culture only items that are possible vectors of transmission.
- Culture the items that make the most sense as the likely reservoir for the organism. For example, outbreaks of *Pseudomonas* should focus on liquid items, whereas outbreaks of *Acinetobacter* should focus on surfaces.

### *Implementing Initial Control Measures*

It is important to remember that the ultimate goal of any outbreak investigation is to halt the adverse events. Thus, it is not only acceptable, but important, to implement a variety of infection prevention measures throughout the course of the investigation. These control measures might be driven by findings from the line list and observations. For example, a strong association with a particular type of procedure or observations of infection prevention breaches during the procedure might lead to immediate alterations in the manner or facility location in which the procedure is performed or even a temporary cessation of the procedure. It is always appropriate to reinforce education on compliance with general infection prevention and control recommendations during any outbreak. In addition to making these initial recommendations, it is vital to develop a plan to ensure compliance with them.

### *Steps of the Follow-up Investigation*

The steps in the initial investigation may need to be repeated multiple times during the course of the investigation. In many instances, these steps are sufficient in controlling an outbreak, and the steps of the “follow-up” investigation are unnecessary. However, there are instances when outbreaks persist despite the initial measures, in these cases, the follow-up steps can become important.

### *Refining the Case Definition*

As the investigation progresses, it may be useful to refine the case definition based on the information gleaned from the initial cases. Ideally, the case definition should be refined to make it as focused as possible on detecting all cases that are potentially associated with the outbreak. This might require that the definition be either narrowed or expanded.

### *Continuing Case Finding and Surveillance*

A methodology should be established to continue case finding efforts. This will be critical in monitoring the progress of the outbreak and in ensuring that it has ended. This surveillance should continue for some period of time (e.g., 1 month) after the outbreak has terminated to ensure that it is truly over.

### *Regularly Reviewing Control Measures*

All infection prevention and control measures that are implemented as part of an outbreak investigation should be reviewed regularly. First and foremost, during the outbreak, compliance with the measures must be reviewed to ensure that recommended control measures are being carried out. In situations in which outbreaks persist and compliance with recommended measures is suboptimal, consideration must be given to how best to heighten compliance. As the outbreak begins to wane, control measures should be critically assessed to determine if and when they can be loosened. This is especially important for control measures that are very time consuming or resource intensive, such as patient-cohorting or dedicating staff to the care of case-patients.

### *Considering Whether an Analytical Study Should Be Performed*

Analytical studies (most often case-control studies in outbreak investigations) are complicated and time consuming and often require access to technical and statistical support. As such, these studies sometimes exceed the resources available to some infection preventionists. Sometimes, an inability to perform an analytical study is cited as a reason that a facility cannot embark on an outbreak investigation without outside assistance. This should not be the case. More often than not, analytical studies are not necessary in the investigation and control of a healthcare-associated outbreak. Rather, they tend to provide statistical support to the cause or causes identified through chart review and observations. However, in some situations, analytical studies can be particularly useful and should be



considered. First, analytical studies can often help guide further investigations and suggest new avenues for exploration in situations in which the source of an outbreak remains unclear and control measures have been ineffective. Second, they might be useful in convincing clinicians that the proposed source or mechanism suggested by chart review and observations is indeed correct. This can be particularly helpful when environmental cultures do not or cannot confirm the source and when the proposed intervention(s) to address the source are resource intensive. Finally, analytical studies are powerful teaching tools and might be undertaken to further the educational experience of trainees in healthcare epidemiology, infection prevention, and public health.

### *Communication During and After an Outbreak Investigation*

Communication within the facility and with public health officials can be critical to the success of an outbreak investigation. In addition to working with public health officials, as described above, there are several important lines of communication within the facility that must be maintained during the course of an investigation.

Clinicians working in the affected areas should be kept abreast of developments and findings and should be queried regularly on any additional thoughts or insights they might have. Not only will this provide important information to help guide the investigation, but it will also help assure HCP that steps are being taken to end the outbreak and will help in establishing the investigation as a partnership between providers and healthcare epidemiology and infection prevention personnel.

Decisions about whether to notify patients about an outbreak must be made on a case-by-case basis in close consultation with facility administration. In some instances, patients may hear about the outbreak or the investigation and have questions about their safety. All facilities should be proactive in preparing for patient inquiries and questions on outbreak investigations and should consider developing patient handouts, fact sheets, and frequently asked questions.

Facility administration should also be informed whenever an outbreak investigation is initiated and should also be updated on a regular basis. In some instances, administrators will need to be educated on the need to investigate outbreaks of single cases or small numbers of cases. It is vital to ensure the support of the facility administration in outbreak investigations because both the investigations themselves and the proposed control measures may require additional facility resources.

Facility risk management personnel also should be informed when outbreak investigations are initiated. Healthcare-associated outbreaks can result in lawsuits, and risk management officials are better able to advise facilities on the best course of action when they are well informed of the outbreak and the investigation. Given the potential for legal action, which may occur many years after the outbreak has concluded, it is important to keep careful records of all of the findings of, and actions taken during, the investigation. It is also often very helpful to keep a detailed time line of events as the investigation unfolds.

Finally, the public relations or press officer, if present, should be kept informed during outbreak investigations. Outbreaks sometimes attract media attention, and the facility must be prepared to handle this should it occur. The press will want to know what the problem is, how it was detected, what the consequences are, and what is being done to investigate and control the problem. If there is no press or public relations officer at the facility, it is often best for the facility to designate one spokesperson to interact with the media. This provides reporters and the audience with a familiar voice for the duration of the outbreak and can help ensure consistent messages delivery. The facility should also develop talking points about the outbreak and the investigation for media interviews.

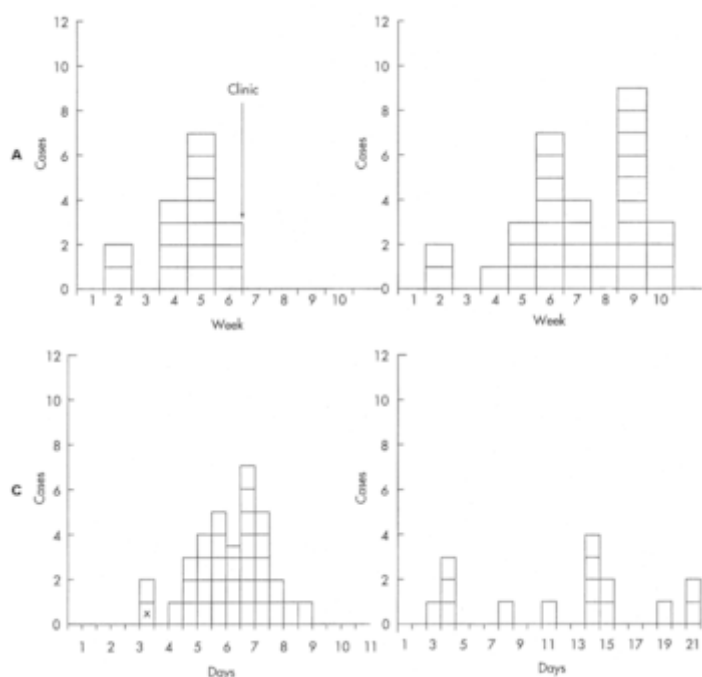
In addition to internal communication, it is important to communicate the findings of and lessons learned from outbreak investigations to the broader scientific community. Communicating the results of outbreak investigations is an important aspect of improving patient safety. Not only are healthcare-associated outbreaks often the result of common factors but current investigations are often aided by the findings from past investigations. Furthermore, outbreaks often help highlight emerging challenges in healthcare. Hence, the findings of outbreak investigations can not only help expedite future investigations but may also help inform policy and regulatory actions to address the root cause of the outbreak. Scientific meetings that accept submission of abstracts, such as the annual APIC meeting, are often ideal forums for the presentation of outbreak investigations, particularly ones in which there was not enough information or local time and expertise to prepare a report for submission for publication in a peer-reviewed medical journal.

## THE EPIDEMIC CURVE

An epidemic curve is a graph in which the cases of a disease that occurred during an epidemic (outbreak) are plotted according to the time of onset of illness in the cases (Figure 12-1). The shape of the curve is determined by the epidemic pattern. The epidemic curve is used to:

- Determine whether the source of infection was common, propagated (continuing), or both.
- Identify the probable time of exposure of the cases to the source(s) of infection.
- Identify the probable incubation period.
- Determine if the problem is ongoing.

An epidemic curve is a histogram. Cases are plotted by date of onset of illness. Time intervals (x-axis) must be based on the incubation or latency period of the disease and the length of the period over which cases are distributed. Inappropriate intervals may obscure temporal distributions (e.g., hours, days, weeks) depending on the causative agent and the length of time the outbreak persists.



**Figure 12-1.**

Epidemic curves; common versus propagated source outbreak.

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Epidemic curves; common versus propagated source outbreak. In practice, other information gathered in the course of investigation is also used to interpret epidemic curves. **A.** Propagated source: Single exposure, no secondary cases (e.g., measles). **B.** Propagated source: Secondary and tertiary cases (e.g., Hepatitis A). **C.** Common source: point exposure (e.g., salmonellosis following a company picnic; food handler 4 times;). **D.** Common source: Intermittent exposure (e.g., bacteremia associated with contaminated blood product). Note: In practice, other information gathered in the course of the investigation is also used to interpret epidemic curves.

## COMMON SOURCE AND PROPAGATED (CONTINUING) SOURCE

## Common Source

A common source means that all cases have the same origin. The same person or vehicle is identified as the primary reservoir or means of transmission. With a common source outbreak, the epidemic curve approximates a normal distribution curve if there are a sufficient number of cases and if cases are limited to a short exposure with maximum incubation of a few days or less (point source). Exposure may be continuous or intermittent. Intermittent exposure to a common source produces a curve with irregularly spaced peaks.

## Propagated (Continuing) Source

A propagated source means that infections are transmitted from person to person in such a way that cases identified cannot be attributed to agent(s) transmitted from a single source. Propagated (continuing) source cases occur over a longer period than in common source transmission. Explosive epidemics resulting from person-to-person transmission may occur (e.g., chickenpox). If secondary and tertiary cases occur, intervals between peaks usually approximate average incubation period.

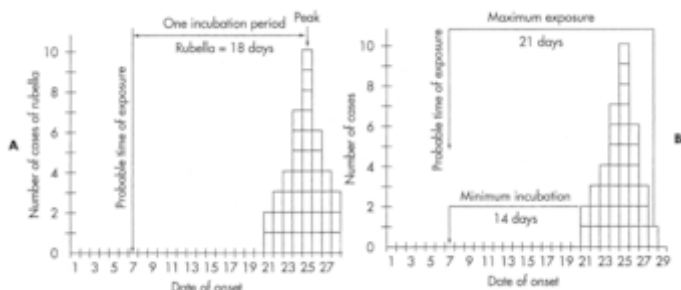
To determine the probable period of exposure of cases in a common source outbreak, it is necessary to know the specific disease involved, dates of onset of cases, and either mean or median or minimum and maximum incubation period(s) for the specific disease.

Draw the epidemic curve and calculate by either of the following methods (Figure 12-2):

1. Using the mean or median incubation period: Identify the peak of the epidemic or the date of onset of the median case. Count back into one incubation period.

or

2. Using minimum and maximum incubation periods: Start with the first case identified and count back in time the minimum incubation period; then using the last case, count back in time the maximum incubation period.



**Figure 12-2.**

Determining the probable period of exposure in common source outbreaks using mean or median incubation period (A) or minimum and maximum incubation periods (B)

[View Image](#)



## USING A CASE STUDY TO REVIEW KEY STEPS IN AN OUTBREAK INVESTIGATION<sup>4</sup>

### Identification of Outbreak

Routine review of microbiological reports of patients identified a bacteremia caused by *Ralstonia* (*Pseudomonas*) *pickettii* in a patient who had recently undergone cardiac surgery. Because this unusual pathogen had not been encountered before at this facility as a causative agent of bacteremia, an investigation was initiated. Five days had elapsed between obtaining the culture and final identification of the organism. In the interim, the patient had been transferred from the intensive care unit (ICU) to a general pediatric unit. All invasive devices had been removed, and her fever had resolved following the initiation of antimicrobial therapy. Because of the infection type, and the fact that *Ralstonia* are

waterborne organisms, a contaminated infusate or intravenous medication was the suspected source of infection. However, microbiological samples of a few injectable medications to which the case patient had been exposed were negative. The infection preventionist alerted cardiac surgery, ICU, and microbiology staff about the case and requested to be notified immediately of any blood cultures that grew *Ralstonia* or other unusual waterborne pathogens and requested that the laboratory save all such isolates.

During the next 2 weeks, two additional surgical patients developed *R. pickettii* bacteremia. Additionally, the microbiology laboratory notified the infection preventionist that *R. pickettii* had been recovered from infusate samples of three patients that had been cultured as part of a study of intravenous (IV) catheter site dressings that was ongoing in the institution. Most patients receiving IV therapy were enrolled in the study and the study protocol included routine culturing of in-use IV fluids. None of these three patients developed any signs or symptoms suggestive of a bloodstream infection. On further review, the laboratory also identified three previous isolates 2 months earlier that grew a nonfermentative Gram-negative bacillus with colonial morphology similar to the *R. pickettii* isolates. However, the study protocol did not require full identification of all organisms if growth was minimal and hence those organisms had not been further identified or saved.

At this time, a preliminary case definition was established: recovery of *Ralstonia* from a culture of blood or an infusate sample among patients at the hospital in the previous 6 months. Because isolates were no longer available for retesting, the three patients identified with Gram-negative bacillus from infusates were designated probable cases. An epidemic curve was plotted. It suggested an intermittent, common source that began in January (Figure 12-3). As required in this state, the institutional outbreak was reported to the state department of health. The state department of health and the CDC were also asked if they had received other reports of cases of *Ralstonia* bacteremia; they indicated that they had not.



**Figure 12-3.**

Epidemic curve for outbreak of *Ralstonia* (*Pseudomonas*) *pickettii* bacteremia and contaminated infusate traced to contaminated fentanyl.

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### Line List

Based on a review of the initial cases and the initial findings, the following information was

included on the initial line list:

#### 1. Demographic data

- Name
- Medical record number
- Age
- Sex
- Diagnosis
- Unit
- Service

- Date of admission
- Date of surgery
- Date of *R. pickettii* culture
- Peak and mean temperatures on the day of surgery and the first 3 days thereafter
- Date of symptom onset

## 2. Risk factors

- Surgical procedure
- Operating room
- Duration of surgery
- Surgical personnel
- Anesthesia personnel
- Vascular access
- Indwelling urinary catheters
- Chest tubes
- Endotracheal tubes
- Prosthetic devices
- Steroids
- Antibiotics
- All IV medications, fluids, and blood

## 3. Host factors

- Renal failure
- Malignancy
- Diabetes
- Heart disease

### *FORMULATION OF HYPOTHESES AND MICROBIOLOGICAL TESTING*

Data from the line list indicated that none of the cases occurred before surgery. This finding, combined with the existing information from the cultures of the infusates and the natural water reservoir of *Ralstonia*, led to the hypothesis that patients had received contaminated IV fluids, blood, or medication in the operating room (OR).

A selective microbiological culture surveillance system was set up that required OR personnel to aseptically remove a small aliquot of IV fluid from each container before administration. The goal of this recommendation was to identify any low-dose, intermittent, intrinsic contamination of fluids commonly used in the OR (e.g., lactated Ringer's solution, dextrose in lactated Ringer's solution).

Microbiological samples were also obtained from in-use multidose medication vials on the anesthesia carts. Other drugs commonly used in operative procedures but in locked storage elsewhere in the OR were also cultured. This included medications such as hydromorphone, morphine, meperidine, methadone, pentobarbital, and fentanyl citrate. Some medications were commercially packaged in unit-dose syringes; others were predrawn from larger ampoules by hospital pharmacy personnel. During the

epidemic, used blood bags were returned to the blood bank and kept in refrigerated quarantine for a designated time period. To rule out the possibility of contaminated blood products, investigators retrieved and cultured the residual contents of the available bags used for implicated patients.

Other microbiological surveillance cultures were taken from environmental sources likely to harbor *Ralstonia*, including faucets, sinks, irrigating solutions, blood-warming baths, and distilled water. Samples for culture were also obtained from the hands of pharmacy personnel who prepared unit-dose medications.

Microbiological samples revealed *R. pickettii* in IV fentanyl (in both the OR narcotic drawer and the central pharmacy) and from one distilled water tap located in the pharmacy. Because OR personnel did not have access to narcotics in the central pharmacy, the findings suggested that the contamination originated in the pharmacy.

### ANALYTIC STUDY (CASE-CONTROL STUDY)

A case-control study was undertaken to test the hypothesis. Nineteen control patients were selected for comparison with the nine patients meeting the case definition (six cases and three probable cases). Controls were randomly selected patients who had surgery on the same day as the cases, but whose cultures of infusion fluids initiated in the OR were negative. (The unrelated IV study protocol in progress at the time required culturing of IV fluids started in the OR. Thus, this information was available.) All nine cases (100 percent) received IV fentanyl, whereas 9 of 19 (47 percent) control patients received the drug ( $p < .007$ ). Although heparin was used significantly more often in the cases than in control patients, it was used for only five of the nine cases (Table 12-1). Cultures of the heparin were sterile. All 9 cases (100 percent) received cefazolin compared to 10 of 19 control patients (53 percent;  $p < .001$ ). This particular drug is widely used outside the OR. However, no cases were identified in patients who had not undergone surgical procedures.

**Table 12-1 . Case-Control Analysis of Risk Factors for Development of *P. pickettii* bacteremia or Contaminated Intravenous Fluid**

	Cases <i>n</i> = 9 (%)	Controls* <i>n</i> = 19 (%)	<i>p</i> value
Age, mean	50 years	46 years	NS
Duration of surgery	4 hours	3.7 hours	NS
Type of surgery	5 (55)	3 (16)	NS
Cardiovascular	4 (45)	16 (84)	
General			
Intravenous fluids	8 (89)	11 (58)	NS
Lactated Ringer's	5 (55)	14 (74)	NS
Dextrose in lactated Ringer's	6 (67)	4 (21)	NS
Saline (9%)	7 (78)	4 (21)	NS
Blood products			
Intraoperative IV medications	4 (45)	3 (68)	NS
Pentathol	5 (55)	5 (26)	NS
Lidocaine	5 (55)	4 (21)	NS
Pancuronium	5 (55)	0 (...)	<0.008†
Heparin	9 (100)	10 (53)	NS 0.001†
Cefazolin	9 (100)	9 (47)	<0.007†
Fentanyl	61.6 mL	16.8 mL	<0.001
Volume of fentanyl, mean			



\*Patients randomly selected who had had surgery on the same day as case but whose cultures of IV fluid from their infusion begun in the OR were negative.

†Fisher's exact test.

*n*, number of cases; IV, intravenous; NS, not significant at  $p < .05$ .

### *FURTHER INVESTIGATION*

It was important to determine whether the fentanyl was intrinsically contaminated (during manufacturing) or extrinsically contaminated by pharmacy personnel while drawing medications into unit-dose syringes. All subsequent cultures of multiple, previously unopened vials of fentanyl tested under controlled conditions were sterile. Query of the manufacturer revealed no knowledge of complaints by other users or an awareness of any quality control problems. Other hospitals using fentanyl from the same source were experiencing no problems. Extrinsic contamination appeared more likely.

Because fentanyl is a potent narcotic subject to illicit use, the question was raised whether the contents of syringes may have been tampered with or diluted for purposes of diverting small portions of the drug without significantly compromising total volume or desired analgesic effect.

Additional tests using liquid chromatography compared concentrations in known sterile, pharmacy-prepared, unit-dose syringes with similarly prepared known contaminated syringes and revealed a lower drug concentration in the contaminated syringes. This verified the suspicion that parts of fentanyl had been removed from the syringes and had been replaced with contaminated distilled water (presumably obtained from the contaminated distilled water tap in central pharmacy).

### *CONTROL MEASURES*

As soon as tampering was confirmed, pharmacy personnel made several changes to increase security. Implementation of these control measures resulted in an immediate termination of the outbreak.

## Conclusions

Investigation of a potential outbreak follows epidemiological principles, as outlined in this chapter. Although the steps may not occur sequentially, the steps should help to guide the infection preventionist in obtaining the goal: to identify potential causes and stop future cases. Reporting requirements for outbreaks vary, and resources are available to assist in the investigation.

## Future Trends

Computerized programs and electronic surveillance data systems continue to improve the early identification of potential clusters of HAIs, management of multidrug-resistant organisms, and enhance antibiotic stewardship programs. Integrating geographical information systems applications may prove to be a powerful tool in helping identify potential problems that merit investigation and help focus investigative efforts. Emerging and reemerging infectious diseases continue to challenge the professionals who track and prevent disease transmission both on a local and global level.

## International Perspective



Reporting requirements and coordination of potential outbreaks with appropriate authorities vary with geographical locale. The infection preventionist should be familiar with these requirements as appropriate to their settings, jurisdictions, and governing bodies.

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# Use of Statistics in Infection Prevention

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## Abstract

This chapter introduces basic statistical knowledge that is directly applicable to the field of infection prevention and control. Although the reader is not expected to memorize formulas or know their derivation, it is important to understand the basic concepts that guide the use of the statistical tests. The formulas presented can easily be found in most statistics books, and most mathematical calculations can be performed with an inexpensive pocket calculator or in a computerized spreadsheet with a computation program. It is suggested that the reader who has never been exposed should study this material with a statistics book for further reference.

## Key Concepts

- A working knowledge of statistics is a requirement for an effective infection prevention and control program.
- Ability to collect, organize, and analyze data is fundamental.
- Appropriate statistical methods must be used if correct interpretation of data is expected.
- Data should be displayed in appropriate graphs and shared with those in the facility who will use the data to improve outcomes.

## Background

### DEFINITION OF DATA

Data are factual information, especially information organized for analysis or used to make decisions. Data is the plural form of datum. When reporting, use the correct form of qualifiers (e.g., *thesedata*; not *thisdata*).

There are two major divisions of data:

- *Discretedata count*(e.g., the number of patients on a ventilator, the number of patients with central lines)
- *Continuousdata measure*(e.g., rate of surgical site infections among patients undergoing colorectal surgical procedures)

DEFINITION OF A DATA SET

A data set is a group of observations whose individual values are connected in some way and are demonstrated in an *array*(a table of data that shows the observations plus the values, as in Table 13-1). In this example, patients are the observations and the number of days signifies the values.

Table 13-1 Example of an

Patient	1	2	3	4	5
No. days	3	10	4	6	20

DEFINITION OF A VARIABLE

A variable is an observable characteristic of a phenomenon that can be measured—a quality, property, or characteristic of the person or things being studied that can be quantitatively measured or enumerated (e.g., age, sex, underlying disease, infections). The dependent variable is influenced or caused by another variable (e.g., ventilator-associated pneumonia [VAP], urinary tract infection [UTI]). The independent variable influences or causes the dependent variable (e.g., ventilator, indwelling urinary catheter). When creating a 2 X 2 table to analyze the data, the dependent variable is on the x-axis (horizontal) and the independent variable is on the y-axis (vertical) (Table 13-2). When creating graphs such as a scatterplot, the independent variable is on the x-axis and the dependent variable is on the y-axis.

Table 13-2 Example of a 2 X 2 Table with the Dependent Variable on the

Treatment	Pneumonia	No Pneumonia	Totals (x)
Respiratory therapy treatment	A	B	A + B
No respiratory therapy treatment	C	D	C + D
Totals (y)	A + C	B + D	A + B + C + D

Basic Principles

WHAT IS STATISTICS?

Statistics involves collecting, organizing, and analyzing data and drawing conclusions on the meaning of the data.

Statistics can loosely be defined as a tool:

- To aid in organizing and summarizing data.
- To communicate findings clearly and meaningfully to others.
- To make inferences about data. Statistics cannot prove either an association or causality; it can merely suggest that an association exists. The strength of the association between cause and effect is determined by computing statistical tests.

## ROLE OF STATISTICS IN HOSPITAL EPIDEMIOLOGY

The infection preventionist (IP) is expected to be the most knowledgeable individual in the facility regarding the current literature on hospital epidemiology. Hospitals frequently decide to initiate a new policy or modify an existing one based on some publication. Some of the questions to be answered include:

- Are the findings statistically significant?
- Was the sample size large enough to demonstrate a difference if there is one?
- Are the groups being compared truly similar?

IPs routinely use statistical methods to prepare reports for the infection prevention and control committee, identify problems or outbreaks, monitor the effect of interventions, identify areas for improvement, and monitor the progress of the improvement. These methods can be used to analyze and describe the occurrence of healthcare-associated infections (HAIs) within the healthcare facility. The IP will need some basic statistical skills to:

- Describe an outbreak (mean, attack rate, possibly standard deviation).
- Select control subjects who are similar to case subjects in regard to possible exposure.
- Identify the distribution of the data (normal, skewed, or unknown) in order to select the appropriate test to determine statistical significance.
- Generate test hypotheses to establish statistical significance of an exposure or increase/decrease in rates.
- Determine the correct graphic display based on type of data (discrete versus continuous).

IPs may wish to do research studies within their facilities. Designing and implementing a study requires knowledge of statistics. (Always consult with a statistician before conducting such a study to make sure that the sample size is large enough to show a difference if there is one and that the appropriate statistical tests are used. Also, obtain approval from the facility's Internal Review Board if patient care practices are involved.) To this end, it is imperative that the infection preventionist has a knowledge and understanding of basic concepts of data and data analysis.

Some commonly used statistical methods are as follows:

- Numeric summaries that describe characteristics of the population being studied (e.g., mean, average number of days of catheterization before development of a urinary tract infection)
- Frequency distributions displayed as tables, graphs, or charts
- Infection rates

## STATISTICAL CONCEPTS, TERMINOLOGY, AND SYMBOLS

There are two types of statistics, *descriptive* and *inferential*.

- *Descriptive* statistics provides numerical information about *variables*. In simple terms, it uses numbers to describe characteristics of a data set.
- *Inferential* statistics make an assumption about a population based on a sample or calculates strength of association between cause and effect.

Descriptive statistics includes two types of data, *discrete* and *continuous*.

- *Discrete* data contain whole numbers and are mutually exclusive (e.g., infected or not infected, male or female, blood type).
- *Continuous* data contain information that can be measured on a continuum or scale and can have numeric values between the minimum and maximum value (a continuum) (e.g., age; serum cholesterol level; temperature; infection rates). Continuous data require the process of measuring, rather than counting (e.g., central line–associated bloodstream infection [CLABSI] rates over a 2-year period) and may contain whole numbers, decimals, or percents.

## Descriptive Statistics

### SCALES OF MEASUREMENT

#### Nominal Scale

The nominal scale is the simplest or crudest level of measurement. Categories are used to classify observations into mutually exclusive groups or classes. No order is implied among the classifications. These observations are known as nominal data (e.g., gender, 1 = male, 2 = female; ill, not ill; infection sites).

#### Ordinal Scale

If observations are ranked so that each category is distinct and stands in some definite relationship to each of the other categories, the observations are known as ordinal data (e.g., unsatisfied, satisfied, very satisfied with socioeconomic class; staging cancer disease severity into class 1, 2, or 3; shortest to tallest).

#### Interval Scales

When data meet all the requirements for ordinal data and the exact distance between any two observations on the scale is known, they are called interval data.

### FREQUENCY MEASURES

#### Measures of Central Tendency

Measures of central tendency describe how observations cluster around a middle value and locate only the center of a distribution measure. The methods include *mean*, *median*, and *mode*.

The most commonly used parameter is the arithmetic *mean* (average). Symbols used include  $\mu$  for population mean and  $\bar{x}$  (x) for sample mean. The formula to calculate the sample mean is:

**Figure 13-1.** Chap13\_page3a.png[View Image](#)

$$\bar{x} = \frac{\sum x}{n}$$

Where:

$\Sigma$  (sigma) is the symbol for "the sum of,"

$x$  is the value of each observation, and

$n$  is the number of observations.

Example: You want to know the average length of stay (LOS) of seven patients (a small sample size is used for the convenience of demonstration). Create a table or array (Table 13-3). Add all of the observations and divide by the number of observations. The average LOS in the array of number equals five.

$$5 = \frac{2 + 3 + 6 + 4 + 5 + 9 + 6}{7}$$

**Figure 13-2.** Chap13\_page3b.png[View Image](#)**Table 13-3** Average Length of Stay of Seven Patients

Patient	Length of Stay (d)
1	2
2	3
3	6
4	4
5	5
6	9
7	6

The mean of a data set is inaccurate if there are extreme values (outliers) in a data set. Most statistical tests use the mean because it is more amenable to mathematical manipulation than the median or the mode. However, because the mean includes the value of each observation, it is the measurement most affected by outliers (unusually high or low values), especially when the number of observations is small. As the sample size gets very large, outliers are less important. Use the numbers in Table 13-3, but instead of a 6-day LOS, patient 7 is the outlier and has a LOS that is 67 days. Now calculate the mean length of stay as shown in the following example.

Example:

Obviously, the value 13.3 is not reflective of the values in the data set. The outlier that had a LOS of 67 days resulted in a dramatic change in the mean value.

*Median* is the point at which 50 percent of the values fall below a middle value and 50 percent of values occur above the middle value. It is the midpoint of the observations. The median ignores extreme values and is better at indicating values close to an average. It is also a good measure for ordinal data or for numeric data when the distribution is skewed. The median absolute deviation (MAD) is a good measure of variability and is not much affected by extreme outliers.



To calculate the median of the first data set in Table 13-3, arrange the data in either ascending or descending order and find the middle value (e.g., for 2, 3, 4, 5, 6, 6, 9, the middle value is 5). Note that the median value would not change in the data with the extreme value of 67.

This method assumes that there are an odd number of values. If the data set has an even number of values, arrange the set in ascending or descending order, find the middle two values, add them together, and divide by 2.

Example:

2, 3, 4, 5, 6, 7

$4 + 5 = 9$

$9 \div 2 = 4.5$

The median absolute deviation is similarly computed by ranking the absolute deviations from the median and finding the median of the deviations (1.5 in this case).

*Mode* represents the observation(s) that occur(s) most frequently in a data set and determines the height and shape of a curve. Data sets may have more than one mode and can be bimodal or multimodal. Small data sets may be nonmodal (e.g., there are no repeated values). The mode is most useful for describing qualitative data (used for nominal data and bimodal distributions). It is the least stable of the three measures of central tendency.

## QUANTILES AND PERCENTILES

### Quantiles or Quantifiable Groupings

Quantiles, or quantifiable groupings, are useful for a detailed study of a variable's distribution.

Quartiles group the values in ascending order such that 25 percent of the observations are in the first grouping, 25 percent in the second, and so forth. Deciles are groupings of 10 percent blocks of the observations, and percentiles are 1 percent groupings.

*Percentiles* are often used in the context of the  $p$ th percentile, with the value having  $p\%$  of the measurements below it and  $(100 - p)\%$  above it. Percentile is used to designate the number in a frequency position below which a certain number of scores will fall. (If 50 people took a test, and you scored better than 40 others, you would be in the 80th percentile, or in the top 20 percent of the group.) The median is a specialized case of a quantile, defined as the 50th percentile.

*Percentage* is the relative frequency of occurrence of some event to a total (e.g., an attack rate is a percentage, number of infections divided by the number at risk in the same time interval multiplied by 100).

## MEASURES OF VARIABILITY

Variability measures how the values are spread around the mean and includes range, deviation, standard deviation, and variance.

- *Range* provides a value that represents the difference between the highest and lowest values in a data set, but it does not say how many observations are in the data set. Like the mode in the measures of central tendency, the range is the least stable measure of dispersion.

Example: Temperatures taken on Patient A document the highest temperature at 103° F and a low reading of 98.6° F. The range is 4.4° F (the difference between 103° F and 98.6° F). A common mistake is to say the range is 98.6° F to 103° F. That is the raw spread of the values. The range indicates the *extent* of the spread.

*Deviation* measures the spread of each individual value from the mean of the data set and is represented by:

$$(X - \bar{X})$$

Where:

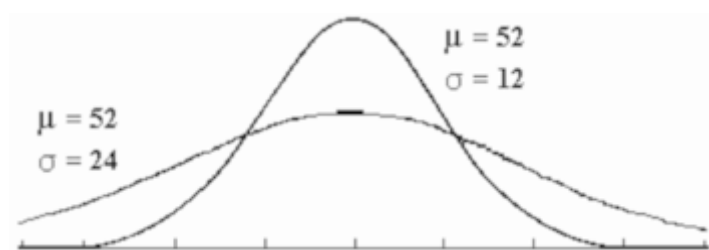
X is the value of each observation and  $\bar{X}$  represents the mean of the data set.

Each individual measurement has three possibilities:

- Negative deviation (less than the mean)
- Positive deviation (greater than the mean)
- No deviation (same as the mean)

The sum of the deviations must always equal 0.

*Standard deviation* is a measure of dispersion of the raw scores that reflects the variability in values around the mean. It employs the squared deviations from the mean (variance), which therefore gives added emphasis to larger deviations. The standard deviation indicates how small the variability is (e.g., the spread) among observations. If the variability is small, all the values are close to the mean. If it is large, the values are not close to the mean (Figure 13-1). A standard deviation is only valid with a data set that has a normal distribution. If results are normally distributed, 68 percent of them will be within a standard deviation of the mean. Both of the curves in Figure 13-1 have the same mean but less precision.



**Figure 13-3.**

Two difference curves showing different standard deviations but the sam

[View Image](#)



**Figure 13-4.**

Formula for the standard deviati

[View Image](#)



$$\sigma = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

The symbol for the standard deviation of the population is  $\sigma$  and for the standard deviation of the sample is  $s$ . The calculation formula is the same for both, with the exception of the sample statistics. When a calculation is based on a sample, there is a risk of underestimating the population parameters. To adjust for this underestimation, we subtract one observation from the denominator ( $n - 1$ ).

Mathematically, the standard deviation of a sample is obtained by taking all the deviations from the mean, squaring them, and then dividing their sum by the total number of observations minus 1, and finally taking the square root of this number.

The formulas for the standard deviation of a population and a sample are shown in Figure 13-2.

Example: Calculate the standard deviation of line days on a sample of five patients. A small sample is used for the convenience of demonstration.

1. Create an array (table) as shown in Table 13-4.

2. Calculate the mean using the formula discussed previously. ( $\bar{x} = \sum x/n$ ). Calculations are shown here:

$$\bar{x} = \sum \frac{(4 + 6 + 4 + 7 + 3)}{5}$$

$$\bar{x} = \frac{24}{5}$$

$\bar{x} = 4.8$  The mean number of line days is 4.8 among those five patients.

**Figure 13-5.** Figure%2013.02b.r [View Image](#)



3. Calculate the deviations for each observation and sum the total (must always add up to 0 in a normal distribution). Why must it add to 0? The mean is the point at which the deviation scores balance, the values on either side of the mean are equal. So the "average" of the deviation scores will always be 0, regardless of

the value of each deviation score. This is shown in Table 13-5.

**Table 13-4** An Array of Line Days of Five Patients

Patient	No. Line Days
1	4
2	6
3	4
4	7
5	3

**Table 13-5** Value Mean Deviation

Patient	LOS (d)	$x - \bar{x}$	$(x - \bar{x})$
3		$3 - 4.8$	-1.8
4		$4 - 4.8$	-0.8
4		$4 - 4.8$	-0.8
5		$5 - 4.8$	+1.2
7		$7 - 4.8$	+2.2
Mean deviation		$\Sigma (x - \bar{x}) = 0$	

4. Square each deviation and sum the total. This calculation is shown in Table 13-6. Each deviation score is squared to eliminate the negative values. That way, a positive value results when all the squared deviations are added.

Using the formula in Figure 13-2, divide the total of the deviations squared by the number of observations minus 1. Calculate the square root. Adding up the positive numbers in the previous step

gave us an "area" measurement. To convert an area measure to a "linear" measure, the type found on a number line (score points), the square root of the sum of the squared deviations is found.

$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{n}}$$

$$s = 1.64$$

**Figure 13-6.** Chap13\_page5.png

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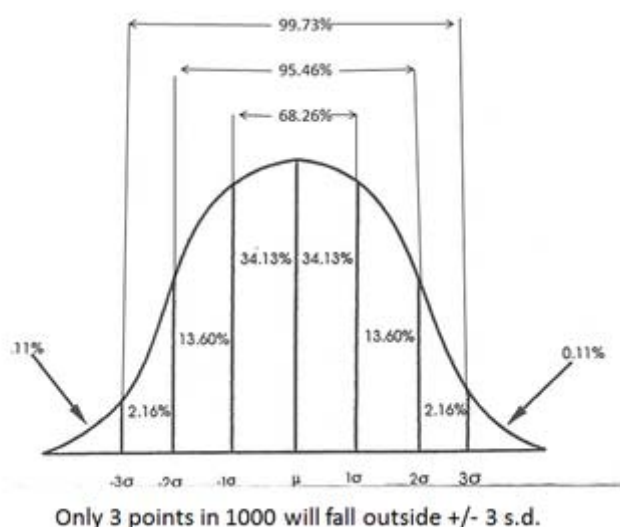


The significance of the standard deviation is that, with normal (bell-shaped) distributions, the following empirical rules for the normal curve apply:

- The interval from one standard deviation below the mean to one standard deviation above the mean contains approximately 68 percent of the measurements.
- The interval from two standard deviations below the mean to two standard deviations above the mean contains approximately 95 percent of the measurements.
- The interval from three standard deviations below the mean to three standard deviations above the mean contains approximately 99.7 percent (or approximately all) of the measurements. Figure 13-3 shows the normal distribution.

**Table 13-6** Sum of Deviations Squared

Patient LOS (d)	(x - $\bar{x}$ )	(x - $\bar{x}$ ) <sup>2</sup>
3	-1.8	3.24
4	-0.8	0.64
4	-0.8	0.64
5	1.2	1.44
7	2.2	4.84
		$\Sigma (x - \bar{x})^2 = 10.8$



**Figure 13-7.**

Normal distribution.

[View Image](#)



The mean and the standard deviation or the variance are necessary to use many of the formulas involved in hypothesis testing (e.g., ztest, ttest).

### Standard Error of the Mean

The standard error of the mean (SEM) is the standard deviation adjusted for by the sample size ( $SEM = \sigma/\sqrt{N}$ ) and is often the better measure for comparative purposes.

### Variance

The variance is the square of the standard deviation of the measurements. The variance is a useful indicator of variability; however, standard deviation is more commonly used. Standard deviation has the same units as the original data.

Example: Square the standard deviation of the previous example to obtain the variance (e.g.,  $1.64^2 = 2.7$ ). The variance of a population is represented by the symbol  $\sigma^2$  and the sample population,  $s^2$ .

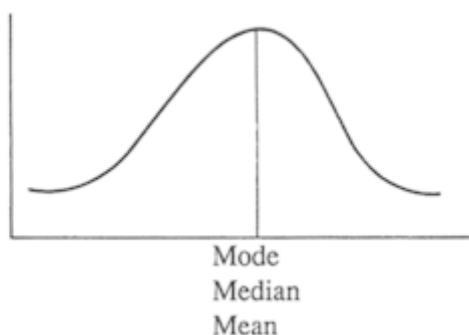
## Coefficient of Variation

The coefficient of variation (CV) is a unitless measure of relative variability and is useful for comparison of populations. It is defined as the ratio of the standard deviation to the mean, expressed as a percentage. The coefficient of variation is meaningful only if the variable is measured on a ratio scale. Because this measure is an index, the CV remains unchanged if all sample values are multiplied by a constant.

## FREQUENCY DISTRIBUTION

If the distribution (spread) of the values is even on both sides of the mean (both halves are equal), it is a *normal* distribution. The curve is bell shaped (Gaussian distribution) and symmetrical. The mean, median, and mode are all equal (Figure 13-4). The normal distribution is the situation in which the population of things or persons clusters around a central point and then trails off symmetrically in both directions with fewer and fewer large and small individuals at the upper and lower ends, respectively. Normal distribution reflects data that are influenced by many small and unrelated random effects. As a sample size increases in number, the effects of the random influences are diminished, and the data get closer to a normal distribution.

For symmetrical curves the mean, mode and median all coincide.



**Figure 13-8.**

Mean = Median = Mode.

[View Image](#)



The distribution (spread) also can be asymmetrical (skewed). The skew indicates the direction that extreme values fall from the mean. The skew can be positive or negative. If the mean is greater than the median, it is a positive skew. If the mean is less than the median, it has a negative skew. References to a left or right skew refer to the direction of the tail of the curve. The shape and height of the curve

are determined by the spread of the values from the mean and the mode (Figure 13-5). When the data are highly skewed, the median more accurately reflects where the bulk of data fall than does the mean. Most computer packages calculate skewness. A value of 0 means there is no skew. A positive number indicates skew to the right, and a negative number indicates skew to the left. In a skewed distribution, note that the median always lies between the mean and the mode.

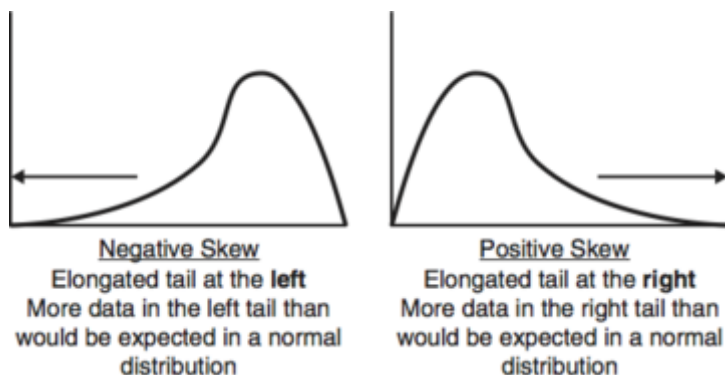
Two terms are used to describe the shape of a frequency distribution: *skewness* and *kurtosis*. Kurtosis refers to how flat or peaked a curve is. The three curves in Figure 13-6 are all symmetric but differ in kurtosis.

*Mesokurtic* is a typical bell-shaped curve or normal distribution.

*Leptokurtic* is the more peaked curve.

*Platykurtic* is the flatter curve.

**Figure 13-9.**



Negative skew (left) and positive

[View Image](#)



**Figure 13-10.** General forms of

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**Figure 13-11.** General forms of

[View Image](#)



**Figure 13-12.**

General forms of kurtosis.

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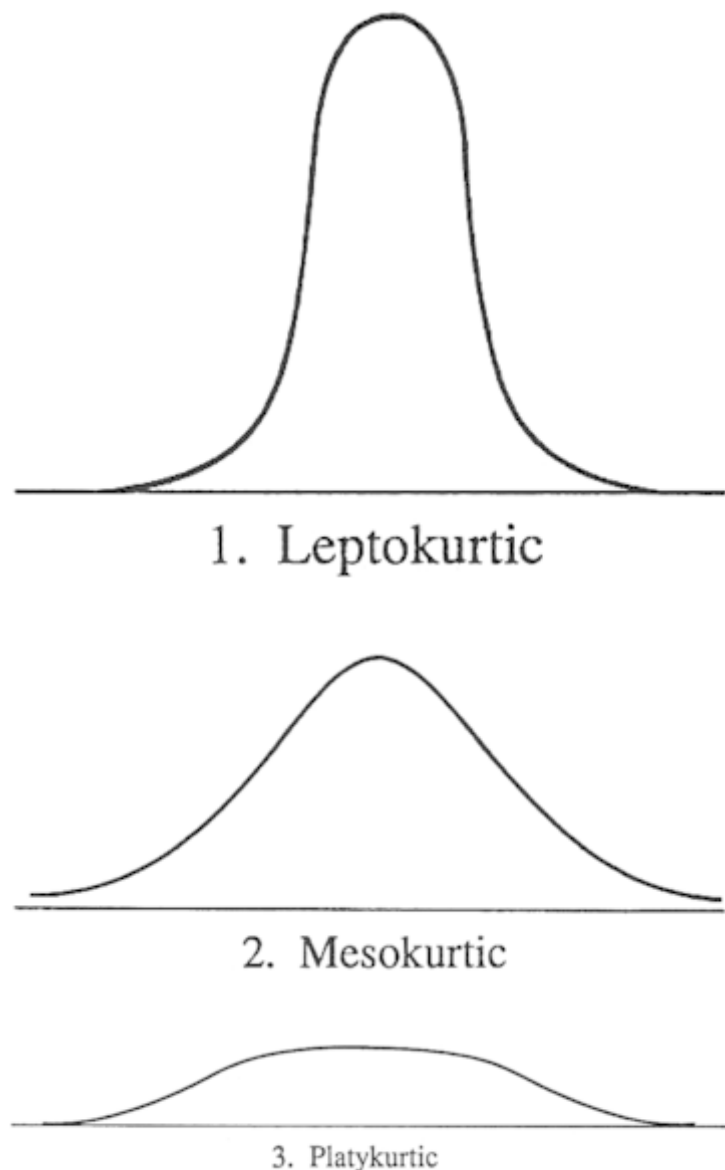
Statistical packages calculate kurtosis. A value of 0 indicates mesokurtosis, positive numbers indicate leptokurtosis, and negative numbers indicate platykurtosis.

## RATES AND RATIOS USED IN EPIDEMIOLOGY

Surveillance generates a data set of numbers (e.g., 7 surgical site infections, 4 cases of ventilator-associated pneumonia, etc.). But numbers of infections do not provide opportunity to identify potential risks or significant variance from baseline.

A rate measures the probability of occurrence (e.g., frequency) in a population of some particular event, such as cases of disease or deaths. Epidemiologists use rates to summarize the experience of a population over time. A rate provides a means of comparing the occurrence of an event in one population to similar populations by adjusting for differences in population sizes.

To avoid inaccurate conclusions from focusing solely on numerators, choice of the appropriate denominator is one of the most important aspects when measuring disease/event. The denominator must only include those at risk for the particular infection being monitored. If you are calculating ventilator-associated rates, your denominator should include patients on ventilators, housed in the same location, and during the same time period.



The types of rate calculations include incidence rates, prevalence rates, point prevalence rates, and attack rates.

### Basic Formula for All Types of Rates

- Rate =  $x/y \times k$

Where:

$x$ = The numerator, which equals the number of times the event (e.g., infections) has occurred during a specified time interval.

$y$ = The denominator, which equals a population (e.g., number of patients at risk) from which those experiencing the event were derived during the same time interval.

$k$ = A constant used to transform the result of division into a uniform quantity so that it can be compared with other, similar quantities. A whole number (fractions are inconvenient) such as 100, 1,000, 10,000, or 100,000 is usually used (selection of  $k$  is usually made so that the smallest rate calculated has at least one digit to the left of the decimal point) or is determined by accepted practice (the magnitude of numerator compared with denominator). The usual value selected for infection rates among patient or device days is 1,000. This standardizes rates for comparisons.

There are three important aspects of the formula:

- Persons in the denominator must reflect the same population from which the numerator was taken.
- Counts in the numerator and denominator should cover the same time period.
- At least in theory, the persons in the denominator should have been at risk of the event or occurrence.

The following discussion shows how to calculate commonly used rates.

## Incidence Rate

Incidence indicates the risk of disease in a population over a period of time. An incidence rate is a way to measure the frequency or extent with which an event occurs in a population over a specified period of time. The incidence rate equals the number of new cases of a disease for a specified time period divided by the population at risk for the same time period multiplied by a constant.

Example: During 2011, 840 patients in Hospital A developed urinary tract infections (UTIs). The hospital had 45,628 total patient days for the year. What is the annual incidence of UTIs per 1,000 patient days?

The incidence rate =  $840/45,628 \times 1000 = 18.4/1000$  patient days.

The formula for incidence rates can also be used to calculate process compliance rates.

Example:

- You monitored hand hygiene compliance for one day.
- You observed 15 opportunities for appropriate hand hygiene practices.
- But hand hygiene was only performed five times
- Rate =  $5/15 \times 100$
- Rate = 33.3 per 100 opportunities or 33.3 percent compliance with hand hygiene practices.

## Prevalence (or Point Prevalence) Rate

A prevalence rate is the proportion of persons in a population with a particular disease or attribute at a specific point in time (point prevalence) or over a specified time period (period prevalence). Prevalence depends on the duration of disease. The prevalence rate equals the number of existing cases of



disease from a specified interval or point in time divided by the population at risk for same time period multiplied by a constant.

To further clarify the difference between incidence and prevalence, incidence rate only includes new cases that developed within the surveillance time period, whereas prevalence includes all cases present during the surveillance period regardless of onset date.

#### SELECTION OF A NUMERATOR FOR PREVALENCE/POINT PREVALENCE RATE

There are two approaches to determining the numerator for prevalence surveys. Both approaches are acceptable provided the composition of the rates is clearly defined. In both cases, the denominator would be the number of charts reviewed, number of patients examined, or the like.

Examples:

- Only active cases of HAI are included in the numerator, that is, all cases from a point in time up to a second point in time are included (e.g., for a 10-day period). This method reduces the prevalence rate and more nearly reflects incidence.

OR

- All HAIs up to a certain point in time are included, whether they are active or inactive, that is, all infections on the day(s) of the study are counted, regardless of their date of onset. This method produces a higher prevalence rate because it counts all cases, regardless of state of infection.

Example: On a specified day, the infection preventionist identifies 16 patients with healthcare-associated UTIs. On the day of the study, the hospital census is 403. What is the prevalence of UTIs per 1,000 patients?

The prevalence rate =  $16/403 \times 1000 = 39.7/1000$  patients.

### Attack Rate

An attack rate is a special form of incidence rate. In fact, it is not truly a rate, but a proportion. It is the proportion of persons at risk who become infected over an entire period of exposure or a measure of the risk or probability of becoming a case. It is usually expressed as a percentage and is used almost exclusively for epidemics or outbreaks of disease where a specific population is exposed to a disease for a limited period of time. In hospital epidemiology, attack rates are also used to describe the probability of acquiring an HAI during hospitalization. An attack rate has no specification of time in the denominator. The attack rate equals the number of new cases of disease (for a specified time period) divided by the population at risk for the same time period multiplied by 100. Attack rate is the same as incidence rate, except that attack rates are always expressed as cases per 100 populations or as a percentage.

Example: During a 34-month period, there were 158 admissions to the burn-trauma unit of a hospital, with 52 of the patients subsequently contracting an infection with *Staphylococcus aureus*. Of the 158 total admissions to the burn-trauma unit, 129 were admitted with burns. The remainder were trauma cases. Of the 52 patients with *S. aureus* infections, 49 had burns. Of the 129 burn patients, 81 had burns that covered less than 20 percent of the body; 48 had burns that covered more than 20 percent of the body. Of the 49 infections in burn patients, 16 were in patients with burns that covered less than 20 percent of the body; 33 were in patients with burns that covered more than 20 percent of their body.

The following rates can be calculated:

- Overall attack rate =  $52/158 \times 100 = 32.9$  percent
- Burn patient attack rate =  $49/129 \times 100 = 38$  percent
- Trauma patient attack rate =  $3/29 \times 100 = 10.3$  percent
- Attack rate for burn patients with less than 20 percent burns =  $16/81 \times 100 = 19.8$  percent
- Attack rate for burn patients with greater than 20 percent burns =  $33/48 \times 100 = 68.8$  percent

## Incidence Density

Incidence density is a type of incidence rate that incorporates time into the denominator. Each person in a group is observed from a fixed beginning time to an established end point. End points include onset of disease, death, loss to follow-up, and end of study. In this case, the numerator is still the number of new cases, but the denominator is different. The denominator is the sum of the time each person was observed during the study, which is totaled for all persons. Another perspective might be the number of persons at risk multiplied by the time for which each remains at risk (e.g., person-time units). Incidence density equals the number of cases (during observation period) divided by the time each person was observed (totaled for all persons) multiplied by a constant.

Incidence density is usually used in cohort studies of diseases with long incubation or latency periods, such as chronic diseases and occupationally acquired diseases, or when people are not followed up for the same length of time. The estimated incidence density for a disease is also called the estimated hazard for developing a disease, person-time rate, or force of morbidity/mortality. Like all quantities meeting the formal definition of a rate, the incidence density is expressed as a change per unit of time.

## Mortality Rate

A mortality rate is the measure of the frequency of death in a defined population during a specified time (usually a year). The crude mortality rate measures the proportion of the population dying each year from all causes. The cause-specific mortality rate measures mortality from a specified cause for a population.

$$\text{Mortality rate} = x/y \times k$$

Where:

$x$ = The number of people in a defined population during a specified interval of time who (1) die of any cause (crude rate) or (2) die of a specified cause (cause-specific rate)

$y$ = Estimated population

$k$ = Usually an assigned value of 1,000 when calculating crude rates: 100,000 is used for cause-specific rates

Example: In a city with a population of 250,000, 2,106 persons died during the year; 12 persons died of bacterial meningitis. What is the crude mortality rate per 1,000? What is the cause-specific rate per 100,000?

- Crude mortality rate =  $2,106/250,000 \times 1,000 = 8.42$  deaths/1000 population
- Cause-specific mortality rate =  $12/250,000 \times 100,000 = 4.8/100,000$  population

## STANDARDIZED INFECTION RATIO

A standardized infection ratio (SIR) is a summary measure that compares HAI rates over time among one or more groups of patients to that of a standard population. SIRs are calculated by NHSN and each SIR is procedure specific and based on specific patient risk factors. The analytical concept is the same as a standardized mortality ratio. It compares how a single healthcare facility's infection rates differ from a national standard.

- Takes data beyond raw rates
- More sensitive with small denominators
- Can combine data
- Adjusts for patients of varying risk
- Compares a facility's actual number of HAIs reported with baseline U.S. data (benchmark)

An SIR can only be calculated if the expected number of infections is one or more. The facility's number of expected is based on their procedure denominator and uses NHSN's aggregate data from the period of 2006 to 2008 for comparison. If your numbers are too small to calculate an SIR, you may want to collect data for a longer period of time.

The calculation formula is *observed number of infections / expected number of infections*.

**Table 13-7** SIR for In-plan ALL SSI by Procedure

OrgID	Outpatient	SummaryYH	Months	Procount	InfcountAll	NumExpAll	SIRAll	SIR_pval	SIRAI
12345	N	2009H2	2	9	2	0.15			
12345	N	2010H2	6	1033	30	10.84	2.77	0.0	1.87–3.2
12345	N	2010H2	6	1111	20	14.25	1.40	0.09	0.88–2.1

In addition to the requirement of an expected number of infections of one or more, there are other criteria that will result in exclusion from the calculation. For the complete list, go to the following NHSN link:

[http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN\\_NL\\_OCT\\_2010SE\\_final.pdf](http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf)

Example: In Table 13-7 there are 10 columns created in a report by NHSN. The columns highlighted in bold contain the calculation reports. Under the column, "numExpAll" is the expected number of infections for the specific month in that facility. The column, "SIRAll" has the calculated SIR.

The first row does not have an SIR because the expected number of infections is less than 1 (0.148); only two rows have an SIR. The row with the SIR of 2.768 (30/10.838) shows a rate that is higher than expected. That increase is statistically significant based on the *p*value of <0.05 and a confidence interval that does not cross 1. The second row with an SIR of 1.403 (20/14.251), while 40 percent higher than expected, is not statistically significant based on the *p*value that is >0.05 and a confidence interval that crosses over 1.

### NHSN SIR Example

In the example in Table 13-7, how is an SIR calculated?

Using the data in Table 13-8, the first step is to calculate an expected number of infections at this center based on the denominator number.

Expected:  $3,467 \times 1.8/1,000 = 6.2$ . Since the expected number of infections of 6.2 is 1 or greater, we can calculate an SIR as follows:

$$\text{SIR} = 5 \text{ observed infections} / 6.2 \text{ expected} = 0.8$$

### Interpretation of an SIR:

SIR of 1: Facility's rates are the same as that expected by NHSN benchmark.

SIR of >1: Facility's rates are higher than the NHSN benchmark.

SIR of <1: Facility's rates are better than the NHSN benchmark.

**Table 13-8** Table 13-8.

Center	# SSI	# Procedures Performed	SSI Rate/1000 Procedures	NHSN Rate/1000 Procedures
GTTST	5	3467	1.4	1.8

## MEASURES OF ASSOCIATION USED TO ASSESS RISK OF DISEASE

Various measures of association are used in epidemiology to quantify the magnitude of the effect of risk factors on disease risk. Epidemiological studies are performed not only to identify risk factors related to disease but also to quantify the magnitude of risk associated with them. The measures of association used most frequently in epidemiology are those based on incidence rates and on the risk of developing disease.

### Relative Risk (Risk Ratio)

Relative risk (RR) is a measure of the strength of association used in prospective and experimental studies. It is the probability of developing a disease if the risk factor is present divided by the probability of developing disease if the risk factor is not present. It is sometimes called the risk ratio or the ratio of the two incidence rates. It estimates how much more likely disease is to occur in exposed groups compared with unexposed ones.

Relative risk:

- Is used for cohort studies (a group of individuals who share a common experience [e.g., central lines])
- Is prospective, starts at point 0 and continues into the future (e.g., begins before the event occurs)
- Asks the question: What is the risk of developing disease if exposed to the risk factor?

Example: At time of admission, 40 patients are followed through to discharge and monitored for the development of pneumonia. Of the 40 patients, 15 developed pneumonia during their stay. Of the 15 who developed pneumonia, 10 were on mechanical ventilation prior to the development of pneumonia. A total of 15 of the 40 patients were on mechanical ventilation.

1. Create a table. Since we are looking at the patients who developed pneumonia and the impact of mechanical ventilation on that development, the table will be constructed as shown in Table 13-9.
2. Enter the known values into the appropriate cells as shown in Table 13-10.

3. Calculate and enter the unknown values as shown in Table 13-11.

**Table 13-9** Patients Who Developed Pneumonia and the Impact of Mechanical Ventilation

	Developed Pneumonia	Did Not Develop Pneumonia	Total
On mechanical ventilation	A	B	R1
Not on mechanical ventilation	C	D	R2
Total	A + C	B + D	

Table 13-10. Known Values Entered Into the Cells

||table:10||

If we enter the values for A (patients on a ventilator who developed pneumonia) divided by R1 (the total number of patients on a ventilator), and divide that number by C (the number of patients not on a ventilator who developed pneumonia) divided by R2 (the total number of patients not on a ventilator) the formula looks like  $RR = (10/15)/(5/25)$ .

Calculate a relative risk using the formula  $RR = (A/R1)/(C/R2)$ .

When the calculations are completed, the  $RR = 3.3$ .

Interpretation: The relative risk of developing pneumonia if exposed to mechanical ventilation is 3.3 to 1 (3.3:1). Those exposed to mechanical ventilation were 3.3 times more likely to develop pneumonia than those who were not exposed to mechanical ventilation.

As a general rule:

- If  $RR = 1$ , there is no significant association.
- If  $RR > 1$ , there is a positive association (worse outcome).
- If  $RR < 1$ , there is a negative association (protective).

## Odds Ratio

The odds ratio (OR) is another measure of association that is closely related to relative risk. It is the probability of having a particular risk factor if a condition or disease is present divided by the probability of having the risk factor if the disease or condition is not present. It is used for all types of studies with nominal data, but is used mostly for retrospective and cross-sectional studies. The odds ratio is sometimes called the cross-product ratio or relative odds.

- OR is used with case control studies. (Begin with subjects who already have event [disease] and compare with those who do not have event [disease].)
- OR is retrospective (disease already present).
- OR looks at prevalence, so it is not appropriate to use with chronic diseases.
- OR asks the question: If disease is present, what is the likelihood of having been exposed to the risk factor?

Table 13-11. Unknown Values Calculated Then Entered Into the Remaining Cells

||table:11||

Table 13-12. Mechanically Ventilated Patients Who Developed Pneumonia and the Impact of Tube Feedings

||table:12||

Example: During a 1-month period, 15 patients developed pneumonia in a 30-bed ventilator-dependent intensive care unit. During the same month, the other 15 patients in the unit did not develop pneumonia. All 30 patients were exposed to mechanical ventilation. Chart review for commonalities revealed that 11 of the 15 with pneumonia had tube feedings, whereas only 2 of the 15 without pneumonia did.

Create a table and enter known values into the appropriate cells as shown in Table 13-12.

Calculate and enter the unknown values as shown in Table 13-13.

Calculate the odds ratio using the formula  $OR = (a \times d) / (c \times b)$

If we enter the information from the table, the formula reads  $OR = (11 \times 13) / (4 \times 2)$ .

When calculations are performed,  $OR = 17.9$ .

Interpretation: The ratio of odds of having tube feedings if pneumonia is present to the odds of having tube feedings if pneumonia is not present is 17.9 to 1 (17.9:1). The odds of having tube feedings if a patient had pneumonia is 17.9 times greater than that among the patients who did not have pneumonia.

## Correlation

Correlation is used to calculate the direction and magnitude of a relationship between two variables. Correlation calculates a value,  $r$ , which measures the degree of the relationship. The calculated values can range between +1 and -1. The closer  $r$  is to  $\pm 1$ , the stronger the relationship. A positive correlation exists when as one variable increases, so does the other (e.g., the longer a urinary catheter is in place, the greater the risk of developing a UTI). A negative correlation occurs when as one variable increases, the other decreases (e.g., increased handwashing results in fewer infections). As  $r$  approaches 0, the less the association between two variables (with a value of 0, there is no correlation).

Table 13-13. Enter the Unknown Values

||table:13||

Table 13-14. Correlation Between Number of Hours Studied and the Test Score

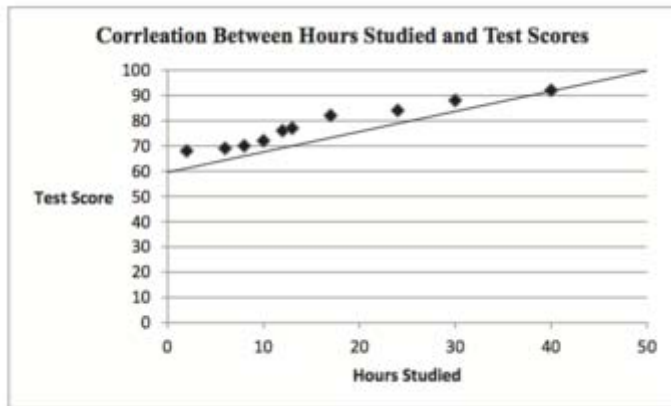
||table:14||

With correlation, both variables are free to vary; the researcher does not control either one. The graphic display would use a scattergram.

Example: Positive correlation: Ten IPs study for the certification exam. All are asked how many hours they studied. After taking the exams, the scores are correlated to the hours studied. Table 13-14 depicts the varying study times and exam scores, and Figure 13-7 plots the information in a scattergram.

## Figure 13-13.





Scattergram demonstrating positive correlation ( $r=0.97$ ) between the amount of hours studied and exam scores.

[View Image](#)



Interpretation: There is a positive correlation between the hours studied and the exam score. As the value of one variable increases, the value of the other variable also increases; the more hours studied, the higher the grade.

Table 13-15.

||table:15||

Example: Negative correlation: For six consecutive months, the IP conducted hand hygiene audits on a specific ICU. At the same time, intensive hand hygiene education was provided once a month. Her study had two targets: Will the education improve hand hygiene compliance before each manipulation of a patient's central line and, if so, will infection rates decline? The starting CLABSI rate in the unit was 2.4 infections per 1,000 line days. Twenty observations were conducted each month.

Interpretation: As hand hygiene compliance increased, infection rates decreased.

Example: No correlation: A study reviewing the relationship between number of patients on mechanical ventilation and the number of patients with CAUTIs in a 30-bed ICU during the month of March 2012.

Interpretation:  $r$  is close to "0." There is no correlation.

**Figure 13-14.**

Scattergram demonstrating a strong negative correlation ( $r=0.996$ ). As one value of one variable increased, the value of the other variable decreased.

[View Image](#)



Table 13-16. Catheter-associated UTI and Patients on Ventilators

||table:16||

## Regression

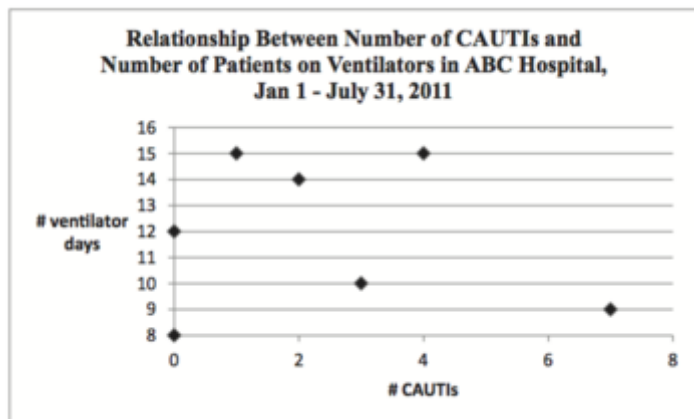
Correlation measures association and describes how a response (dependent variable) evolves as the influence (independent variable) changes.

Regression assesses the influence of one or more variables on another. If there is only one independent variable, the relationship is expressed in a straight line (linear regression). Only one variable is free to vary; the other is controlled by the researcher (e.g., new drug treatment). It is an inferential procedure, meaning you can draw conclusions about a population based on a sample. A straight line can be represented by the following equation:  $y = a + bx$ , where  $y$  is the variable on the vertical axis,  $x$  is the variable on the horizontal axis,  $a$  is the  $y$  value where the line crosses the vertical axis (intercept), and  $b$  is the amount of change in  $y$  (slope).

## Lurking (or Confounding) Variables



Correlation and regression show only association and do not prove causation. Both correlation and regression have limits on predictions called "lurking" or "confounding" variables. It is a variable that has an important confounding effect on the result but is not among the variables being studied. A lurking variable can suggest a false relationship between variables, or it can hide a relationship that exists.



**Figure 13-15.**

Scattergram: number of catheter-associated UTIs and number of patients on

[View Image](#)



Example: A group of college students enrolled in a geriatric course wanted to study depression in the elderly. To capture a constant population, they decided to work with residents of a nearby long-term care facility. Their project focused on providing books with positive plots to the residents. On the first visit, the students administered a psychological test designed to measure depression. Every Wednesday for the

next 3 months, they provided a new book assignment, and the visits ended with group discussions on the stories read. At the end of the study period, the same test for depression was administered, and a statistically significant improvement was noted.

This result did not surprise the facility's administrators because they said that the overall improvement in mood was noticed in better appetites, more interaction among the residents, and fewer physical complaints. The students concluded that reading books helped alleviate depression.

What factors not included in the study could have resulted in the outcome? Could it have been the actual visits by the students? That is very possible because the administrators noted a return to the mood levels prior to the study once the visits stopped. This occurred even though an extensive library was provided for the residents.

## Inferential Statistics

Inferential statistics makes an assumption about a population based on a small sample size and is used to show an association between cause and effect (e.g., development of pneumonia and being on a ventilator). There are calculations to show the strength of the association between the cause and effect, but cause can NEVER be statistically proven. There are only methods to validate the strength of the association. Inferential statistics is part of our everyday life and used in election polls, medical testing, environmental monitoring, and manufacturing quality control. Inferential statistics relies on probability (laws of chance). The history of probability dates to early Egypt where it was developed to increase the odds of winning in a game of chance (gambling). The first written document on probability dates to the Roman emperor Claudius (circa 60 BC), who wrote on how to win in a game of dice.

## COMPARING POPULATION AND SAMPLE

### Population

Population is the set of all observations of interest to the investigator (the universe). These may be individuals, procedures, or any type of measurement. The population (sometimes called parent

population) is the total from which the sample is selected (e.g., all hospitalized patients, all burn patients).

## Sample

The sample is a group of observations selected from a population and chosen to represent the population whole. The values in a sample are those that are actually observed and measured by the researcher.

Generally, the larger the sample, the stronger the inference. Variability is inversely proportional to the square root of sample size; therefore, as the size of the sample increases, variability decreases. The larger the sample, the less likely that the observed difference is due to chance alone; small samples are more subject to error.

## Definition of Power and Its Relationship to Sample Size

The power of a test is its ability to detect a specified difference (e.g., the probability of rejecting the null hypothesis when it is false). The greater the specified differences to be detected are, the more powerful a sample will be in its ability to reject a false null hypothesis.

Because statistical testing for significant differences is based on the number of outcomes, a researcher must always determine how much of a difference might be expected (the power of the test) to calculate the power of the test and to determine a sample size appropriate for the study. The smaller the difference expected, the less the power of any given sample size has to detect a true difference.

Determination of sample size involves simultaneous consideration of risk factor frequency, disease frequency, and desired degree of sensitivity. A study to detect a slight difference or slight increase in disease risk with great precision will require more individuals than for less precise detection of large differences.

## SAMPLING DISTRIBUTION

Inferential statistics assumes some type of sampling distribution (normal or skewed) against which the observed data from sampling are compared. Statistical inference based on the normal distribution, sometimes referred to as the bell-shaped curve, is the type most frequently encountered in the literature. In the day-to-day surveillance and data collection conducted by infection preventionists, the sample sizes (number of infections) are usually small and a normal distribution cannot be assumed. The test for each type of data, normal distribution and distribution unknown, is reviewed in this chapter.

## HYPOTHESIS TESTING

A common use of statistics is hypothesis testing. It is a statement of expected results. Hypothesis testing uses the distribution of a known area in the normal curve. It estimates the likelihood (probability) that a result did not occur by chance. First, a research or alternate hypothesis is formulated. The hypothesis states the expectation to be tested (e.g., Doctor A has a higher surgical site infection rate than does Doctor B). Then a statement that is opposite to the research or alternate hypothesis is developed (e.g., Doctor A has a lower infection rate than does Doctor B). The latter is called the null hypothesis ( $H_0$ ). The  $H_0$  is always stated to be rejected. The research or alternate hypothesis ( $H_a$ ) is the desired result. Only two outcomes are possible with hypothesis testing: The null hypothesis is accepted or rejected.

To test a hypothesis, the cut-off value must be selected in advance. Do you want to be 95 percent certain that your result did not occur by chance (selecting to two standard deviations)? This would tell

you that there is still a 5 percent chance that your results did occur by chance. This number is called the critical or tabled value because it is looked up in a table. If the null hypothesis can be rejected, that is taken as evidence in favor of the alternate hypothesis. Because a test is rarely conclusive, one cannot state that the alternate hypothesis has been "proved," only that the theory has been supported.

Directional hypothesis specifies the expected relationship between variables. It can be one- or two-tailed (Figure 13-10).

One-tailed example: Direction is specified in advance. Concern is with only one direction from the mean.

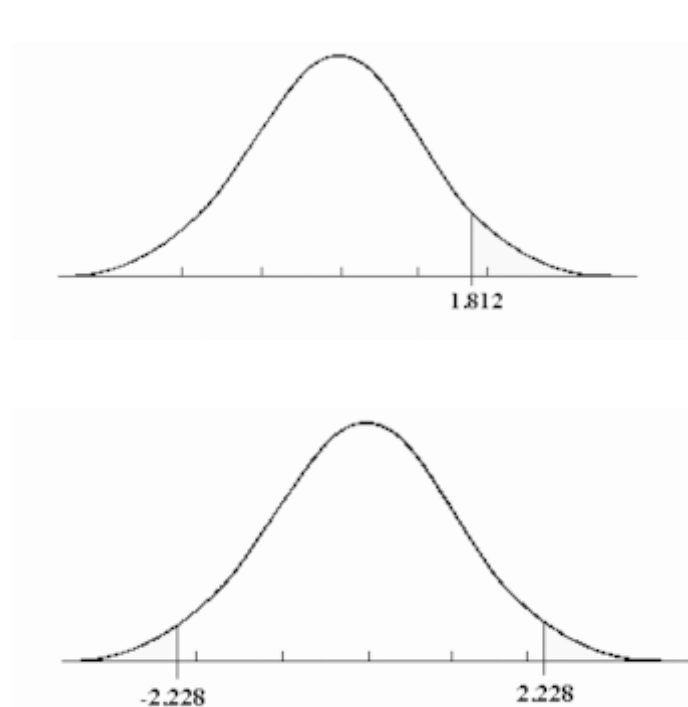
Research hypothesis: Doctor A has a higher surgical site infection rate than does Doctor B.

$H_0$ : Dr. A infection rate  $<$  Dr. B

$H_a$ : Dr. A infection rate  $>$  Dr. B

When the intent is to test whether the true population mean is significantly greater than the value hypothesized under the null hypothesis, the rejection region is one-tailed in the upper tail or right-hand side. When the intent is to test whether the true population mean is smaller than the value hypothesized by the  $H_0$ , the rejection region is in the lower tail or left-hand side. When the direction is predicted, one-tailed tests are preferable to two-tailed tests.

Two-tailed example: Direction is not specified. Concern is with difference in both directions, regardless of the direction.



**Figure 13-16.** Figure%2013.10A [View Image](#)

**Figure 13-17.**

Data display examples for directional hypotheses.

[View Image](#)

Research hypothesis: The surgical site infection rate for Doctor A is not the same as the infection rate of Doctor B.

$H_0$ : Dr. A infection rate = Dr. B

$H_a$ : Dr. A infection rate  $\neq$  Dr. B

When interest is to determine if the true mean is either greater than or less than, that is, in any way different from, the value hypothesized under  $H_0$ , the rejection region consists of two tails.

The rejection region for a one-tailed test is determined by placing the entire alpha level in one tail to find the cutoff point calculated for a test statistic value in the appropriate statistical table.

The decision to select a one-tailed or two-tailed test is not purely statistical.

There are risks associated with hypothesis testing, as shown in Table 13-17.

A type I error ( $\alpha$ ) means rejecting the null hypothesis when it is true and attributing significance when there is none. The probability of committing a type I error is referred to as the *significance level*. The  $\alpha$  level is always stated.

A type II error ( $\beta$ ) means accepting the null hypothesis when it is false or not attributing significance when it exists.

The following shows ways to reduce the risk of errors:

Type I ( $\alpha$ ) error can be reduced by decreasing the length of the "rejection" area. Keeping the  $\alpha$  level very small (e.g., 0.05, 0.01) will decrease the risk of committing a type I error.

Type II ( $\beta$ ) error can be reduced by increasing the sampling size. Recall that as the sample size increases, the data get closer to a normal distribution. With infection control data, sample size cannot be controlled (e.g., number of infections, number of line days). It may not be obvious when a  $\beta$  error has been met.

Types I and II errors are inversely related. Once the sample size is fixed, decreasing the risk of committing a type I error increases the risk of committing a type II error. Therefore, it is impossible to control for both types of errors simultaneously.

## TYPES OF INFERENTIAL STATISTICS

Inferential statistics are divided into two types: parametric and nonparametric.

Table 13-17.Risks Associated With Hypothesis Testing

||table:17||

### Parametric Tests

Parametric statistics assume a normal distribution of the parent or sample population. Most parametric techniques require measurements on a continuous-interval scale. There are many statistical tests in each category, but the two examples that have application for infection prevention and control are the ztest and Student's ttest. The formulas can be found in any statistics book and will not be detailed in this text.

The ztest is the most appropriate to test that the means of two samples are not different (two-tailed hypothesis). An example of its use is to compare the mean of infection rates against the NHSN mean or another benchmark mean. It requires a normal distribution and a sample size of 30 or more.

An English statistician, W.S. Gossett, working in Dublin for the Guinness brewery and writing under the pseudonym "Student," developed the ttest named for him for quality control in brewing. Student's ttest also works best with a normal distribution, but it can be used when the sample size is less than 30. It can be used with continuous data (e.g., infection rates) and can be one- or two-tailed. There are two types of ttests:

- Independent sample: experiment versus a control
- Paired sample: two measures from the same sample (e.g., before and after)

While the formulas for the ztest and ttest are not detailed in this chapter, degrees of freedom (df) must be mentioned if calculations are to be performed manually. The degree of freedom is a parameter used to help select the critical value in some probability distributions. It is necessary to know the df to select

the correct critical value from the table. The formula to calculate degrees of freedom can be found in any statistics book.

## Nonparametric Tests

Nonparametric data make no assumption about the distribution of the population values and can be used with discrete data (e.g., infection, no infection), nominal and ordinal data, and interval data. The main advantage of nonparametric methods is that the assumptions of normality are not required.

One nonparametric statistical technique to test an association is called the chi square ( $\chi^2$ ) test. The  $\chi^2$  test can analyze two or more groups and measures the observed (the interest of study) against the expected (baseline, benchmark, or historical data).

Figure 13-11 shows the formula for chi square.

O is the observed frequency.

E is the expected frequency.

$$\chi^2 = \frac{(O - E)^2}{E}$$

Figure 13-18. Figure%2013.11.png

$$\chi^2 = \frac{(O - E)^2}{E}$$

Figure 13-19.

Formula for chi square.

Table 13-18.2 X 2 Table

||table:18||

[View Image](#)



[View Image](#)



Chi-square distributions are positive numbers and are skewed to the right.

A  $\chi^2$  test can be used to compare any number of proportions.

The  $\chi^2$  test is appropriate when comparing infection rates of Doctor A versus Doctor B, as mentioned in the section addressing hypothesis testing. It also can be used to support a theory that the infection rate calculated during the current month is higher than the baseline (previous months).

Example: There is a sense the current month's ventilator-associated pneumonia (VAP) rate is higher than the rates of prior months. The immediate past month had 15 patients who developed VAP of 60 patients who were on ventilators.

Data from the previous 12 months documented 8 patients with VAP of 103 patients who were on ventilators. The null hypothesis is stated to be rejected: The current VAP rate is not different from the baseline.  $H_0$ : Current rate is equal to the baseline rate. The alternate (desired outcome) hypothesis is stated as "the current VAP rate is different than the baseline."  $H_a$ : Current rate is not equal to the baseline rate (two-tailed). A 95 percent level of significance level is selected (a 5 percent [1 of 20] risk of being wrong, rejecting the null hypothesis when it is true).

1. Create a 2 X 2 table (Table 13-18).
2. Enter the known values into the cells in the row "current" (15 into cell A under VAP, 60 under the "total" heading), in the row "baseline" (8 into cell C under VAP and 103 under the "total" heading) (Table 13-19).

3. Calculate the values for cells B and D by subtracting the value in cells A and C from the row totals (Table 13-20).
4. Total the two columns (A + C and B + D).
5. Total the two rows (A + B and C + D).
6. Total all rows and columns (A + B + C + D) as shown in Table 13-21.
7. Calculate the degrees of freedom. The formula for calculating degrees of freedom for a  $\chi^2$  test is as follows:  $C_n - 1 \times R_n - 1$  ( $C_n$  represents the number of columns and  $R_n$ , the number of rows). In a 2 X 2 table (two rows and two columns), the formula would be  $2 - 1 \times 2 - 1 = 1$  df.
8. Plug in the values using the formula for  $\chi^2$ .
9. Find df of "1" in the column on the left side of the table. Go across the row to the right until you find a value closest to your calculated result. The calculated (computed) result is 7.92. The closest calculated value is between 7.88 and 9.14 in the table. The *p* values above 7.88 and 9.14 are 0.005 and 0.0025, respectively. With a two-tailed test for a 95 percent probability that the result did not occur by chance, a *p* value of .025 is needed to be met ( $0.05/2$ ). The calculated result exceeds that minimum requirement, so the  $H_0$  can be rejected with a 95 percent probability that the result did not occur by chance.

Table 13-19. Known Values

||table:19||

Table 13-20. Calculate Missing Values

||table:20||

When calculations are done manually or using a calculator, the appropriate table must be used to verify the result (i.e.,  $\chi^2$  critical values table for  $\chi^2$ ). The value in the appropriate table is called the critical value (Table 13-22).

The Fisher's exact test is used in place of the  $\chi^2$  when the sample size number is less than 20 or any one cell in the table is less than 5 (Table 13-23).

## DEFINITION OF TEST STATISTIC

A test statistic is a numeric measure computed from a set of sample measurements that quantifies the magnitude of discrepancy between the hypothesized population parameter and the statistic computed from the sample. It can be converted to a probability value (i.e., level of significance) using special tables. Different test statistics (e.g.,  $\chi^2$ , *t* test) use different statistical tables for interpretation of significance. A *p* value is not the probability that an observed result is due to chance alone. Instead, it is the probability, given that the null hypothesis is true, of collecting a random sample of the same size from the same population that yields a test statistic at least as extreme as the one calculated from the sample.

Table 13-21. Totaling All Rows and Columns

||table:21||

Table 13-22.  $\chi^2$  Critical Values Table



||table:22||

## DEFINITION OF LEVEL OF SIGNIFICANCE

The level of significance is the probability value arbitrarily chosen by the researcher as the desired level of probability at which one may feel secure in rejecting the null hypothesis. When using sample data, it is not possible to be absolutely certain that the hypothesis being accepted is true. Therefore, a probability that the finding is due to chance is stated. This probability of rejecting a null hypothesis when it is true is the level of significance or  $\alpha$  level. Most researchers use .05 (5 percent) or .01 (1 percent) values for  $\alpha$  to minimize the chances of incorrectly rejecting the null hypothesis. This specified level states a sufficiently small likelihood that the given observation could occur by chance variation alone (e.g., .05 or a 1-in-20 chance). The researcher finds the appropriate rejection region for a test statistic at a given  $\alpha$  level and rejects the null hypothesis for those values of the test statistic that lie beyond the specified value. Simply stated,  $\alpha$  level is the level of risk. It is the level of risk a researcher is willing to take of being wrong.

## CONFIDENCE INTERVALS

A sample mean is an estimate of the population mean ( $\mu$ ). It is a point estimate that may include some error. To compensate for this margin of error, a calculation is performed to identify a range of possible values the population mean might take. This range is known as the confidence interval (CI ).

To calculate a CI, the data must have a normal distribution. The researcher determines what level of confidence to select. The common selection is 95 percent (e.g., you want to be 95 percent certain the outcome did not occur by chance). The formula for calculating a CI of a sample is as shown in Figure 13-12.

The result will give a plus and minus (a, b) value because one value will be less than the sample mean and the other greater than the mean (a range is being calculated).

Table 13-23.Fisher's Exact Test

||table:23||

The zscore is a unit of measurement and is commonly used for standardized observations that tell us how many standard deviations the original observation falls from the mean and in which direction. The value for the zscore is found by going to an "Areas of the Standard Normal Curve" table.

Example: You are participating in a program to monitor obesity among the male senior students from a local high school. The enrollment number of male seniors is 320. You take a sample of 100 seniors and weigh them. You calculate a mean of 177 lb and a standard deviation of 28 lb. You want to be 95 percent certain that the sample mean is a true reflection of the mean of all senior male students. You are aware that the mean from the sample is a point estimate, and you want to increase the accuracy of your result by calculating a possible range of weights.

Calculate the zscore: For a 95 percent confidence that the result did not occur by chance, the first step is to divide .95 by 2, for a result of 0.4505 (remember, you are looking for a plus and minus value) and go to the table and look for the z score that corresponds to 0.4750 and you find that the zscore is 1.96.

Plug the numbers into the formula:

$$95\% \text{ CI} = 177 \pm (1.96 \times 28 / \sqrt{100})$$



$$= 177 \pm (1.96 \times 28) / 10$$

$$= 177 \pm 5.5 \text{ lbs}$$

Interpretation: We can be 95 percent certain the mean weight of all senior male students is between 171.5 and 182.5 lbs.

## DEFINITION OF REJECTION REGION

The rejection region of a test of hypothesis specifies which values of the test statistic are "sufficiently large" to warrant rejection of the null hypothesis. The size of the rejection region depends on the level of significance for the test (Figure 13-13).

$$95\% \text{ C. I.} = \bar{x} \pm (z * SE)$$

$\bar{x}$  is the mean

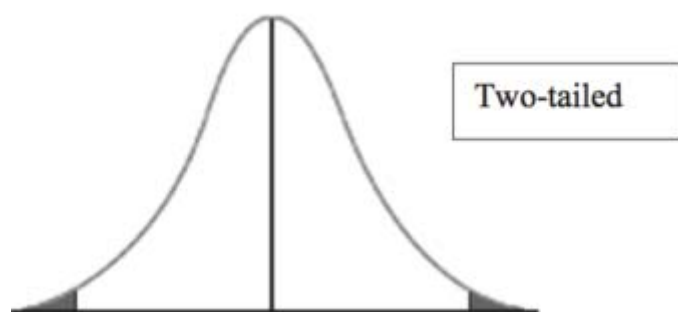
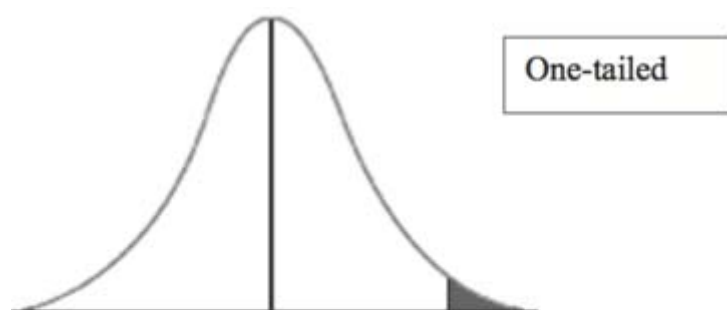
$z$  is 1.96 (from the table)

SE is the standard error of the mean =  $SD/\sqrt{n}$

SD is the standard deviation

$n$  is the number of observations

$$95\% \text{ C. I.} = \bar{x} \pm (1.96 * SD/\sqrt{n}) = \bar{x} - (1.96 * SD/\sqrt{n}) \text{ to } \bar{x} + (1.96 * SD/\sqrt{n})$$



hypothesis. There is not sufficient evidence that sampling variation is the likely explanation for difference between  $H_0$  and sample values.

**Figure 13-20.**

Formula for confidence interval.

[View Image](#)



**Figure 13-21.**

Area of rejection.

[View Image](#)



## DRAWING CONCLUSIONS FROM STATISTICAL TESTS

### Statistical Significance

The question is: "Is chance or sampling variation a likely explanation for the difference between a sample statistic and the corresponding null hypothesis population value?" If the answer is yes, it means that the difference is likely to occur by chance alone, and this sample result is compatible with the null hypothesis and therefore is *not statistically significant*. If the answer is no, it means that the observed difference is not likely to occur by chance variation, and the sample result is not compatible with the null hypothesis and therefore is statistically significant.

Statistically significant: Reject the null hypothesis because there is sufficient evidence to support that sampling variation or chance is an unlikely explanation for difference between  $H_0$  and sample values. This does not prove that the null hypothesis is true.

Not statistically significant: Do not reject null

Remember that the null hypothesis of a statistical test refers to the parameter(s) of the population(s) of interest. The test statistic that is to be calculated from sample data has a distribution, called the sampling distribution. To understand this distribution, consider a population of numbers from which you take all possible samples of a particular size  $n$ . From each of these samples, you can calculate a test statistic to test some null hypothesis (perhaps that the mean of the population is 0).

These test statistics will not all be equal; they will have a distribution (perhaps a  $t$ -distribution). Thus, it may be possible to calculate the probability of collecting a sample where the value of the test statistic is greater than (or less than) or equal to some specified value. The  $p$ -value will be the probability of observing a sample in which the test statistic is greater than or equal to the test statistic for the sample which you actually did observe. For a one-tailed test, this probability is equal to the area under one tail of the distribution; for a two-tailed test it is the area under both tails.

- If the  $p$ -value is small, you can conclude that the null hypothesis of your test is probably not true.
- If the  $p$ -value is large, you do not have sufficient evidence to reject the null hypothesis.

The  $p$ -value is commonly compared to  $\alpha$ , the specified significance level of the test. If  $\alpha = .05$ , then a  $p$ -value less than .05 would cause you to reject the null hypothesis, whereas a  $p$ -value greater than .05 would cause you to fail to reject the null hypotheses.

## Steps in Performing a Statistical Test

1. Collect the data to be analyzed.
2. Organize the data set.
3. Develop the assumptions required (e.g., normal distribution).
4. State the null hypothesis ( $H_0$ ).
5. State the significance level (usually 0.05 or 0.01).
6. Determine if one-tailed or two-tailed test is appropriate.
7. Select the rejection region (critical ratio).
8. Calculate the appropriate test statistic and its  $p$ -value.
9. Accept or reject the null hypothesis. Use caution: One should use the  $p$ -value as an indication of the strength of evidence against the  $H_0$ .

## Graphic Display of Data

Graphic or pictorial statistics present the numerical data that have been collected in graphs or charts, creating a picture of the data.

There are two types of readers of infection reports: those who want the details and those who want a quick picture. To accommodate those who only want a visual display of data, it is important to select the graph appropriate to the type of data: *discrete* or *continuous*.

When creating graphs, title the chart with the topic of the data, the facility and the time frame including the data. Label the  $x$  and  $y$ -axes and annotate where indicated. Look at the chart and ask, will I know

what information I was trying to share? or if someone were to look at it and you were not present to explain, will they know what information is displayed in the graph?

**Figure 13-22.**

Bar chart.

[View Image](#)



**Figure 13-23.**

Pie chart.

[View Image](#)



With *discrete data*, the most frequently used graphic displays are bar charts and pie charts.

Bar charts compare the size and magnitude of the differences. The bars are unconnected, depicting data that are mutually exclusive. Bar charts display qualifying (names) and quantifying (numbers) data (Figure 13-14).

Pie charts have an advantage over bar charts of depicting what portion of the total each item represents. The portions (slices) of the pie must add up to the total of the whole (pie). If the slices are displayed as percents, the totals must add up to 100 percent (Figure 13-15).

With *continuous data*, ogive (line chart), frequency polygon, or histogram is the most

appropriate selection. In a histogram, the bars are connected, representing a measurement of the same observation (or variable) over time.

**Figure 13-24.**

Ogive.

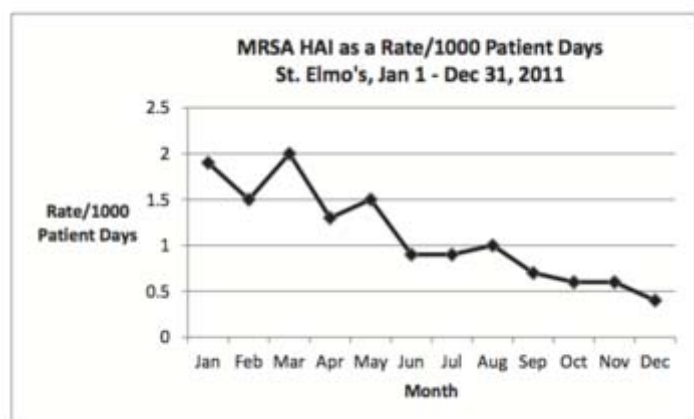
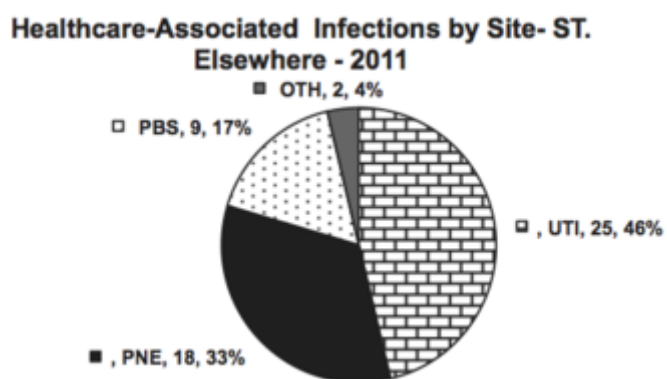
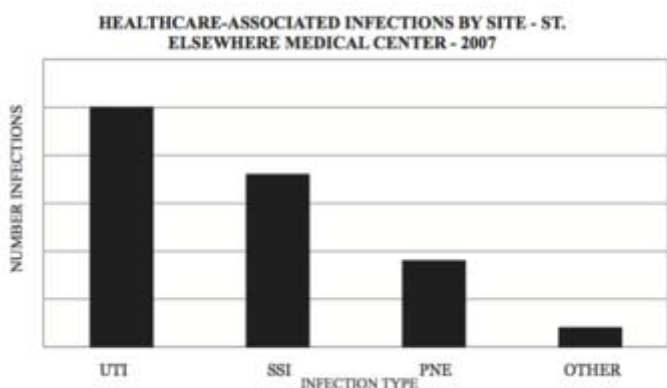
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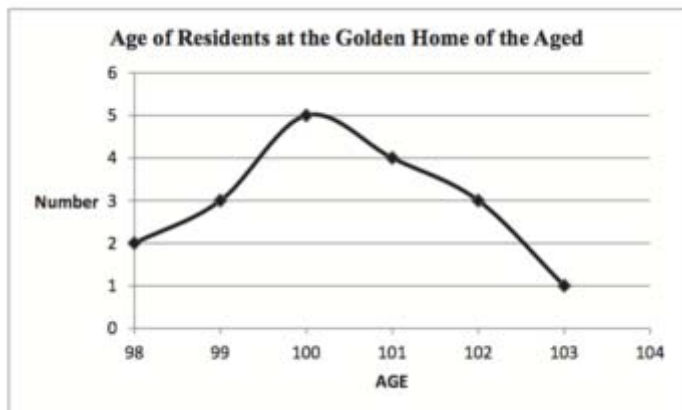
An ogive is a cumulative line graph that plots data points over time (Figure 13-16). Frequency polygons and histograms show how many events occur in each category. The method involves grouping data into frequency intervals and is used to condense large data sets into manageable numbers. With large data sets, more intervals are used to avoid misrepresentation of the distribution of the data. With smaller data sets, fewer intervals are

needed. Once again, it must be stressed that the example in Table 13-24 contains a small sample for the convenience of demonstration.

Both frequency polygons and histograms place the data point over the center point of the data range. With a frequency histogram, the bars are connected and placed so that the center of the bar is placed over the midpoint of the intervals (Figures 13-17 and 13-18).



Create a frequency polygon and a histogram using data in Table 13-24.



**Figure 13-25.**

Frequency polygon.

[View Image](#)



**Figure 13-26.**

Histogram.

[View Image](#)



## Testing for Reliability

### SENSITIVITY, SPECIFICITY, AND PREDICTIVE VALUES

Sensitivity and specificity are common statistical measures to describe diagnostic tests or presence of disease and are related to the main types of hypothesis error. The sensitivity controls the rate of false negatives, which are known as type II errors and the specificity controls the rate of false positives, type I errors.

#### Definitions

**Sensitivity**– Measures the probability that a test correctly identifies patients who have the disease as positive.

**Specificity**– Measures the probability that a test correctly identifies patients without disease as negative.

Rule of thumb: A high sensitivity test is when a negative rules out disease and a high specificity test is when a positive rules in disease.

**Positive predictive value (PPV)**– Measures the proportion of individuals with a positive test who have the disease.

**Negative predictive value (NPV)**– Measures the proportion of patients without disease who test negative.

Table 13-24.

||table:24||

Table 13-25. An Example of a 2 X 2 Table Showing the Process for Determining Sensitivity and Specificity Disease

||table:25||

PPV and NPV are influenced by the specificity and sensitivity of the screening test and by the prevalence of disease in the population.

### Formulas

$$\text{Sensitivity} = \text{TP}/(\text{TP} + \text{FN})$$

$$\text{Specificity} = \text{TN}/(\text{TN} + \text{FP})$$

$$\text{Positive predictive value} = \text{TP}/(\text{TP} + \text{FP})$$

$$\text{Negative predictive value} = \text{TN}/(\text{TN} + \text{FN})$$

Specific example: The pharmaceutical company Drugs R Us is researching a test to identify severe acute respiratory syndrome (SARS). The company screened 203 people who were admitted to a hospital with a diagnosis of "rule out" SARS. Table 13-26 shows application of this concept using the following numbers: TP = 2, TN = 182, FN = 1, FP = 18.

Using the formulas mentioned previously:

$$\text{Sensitivity} = 2/(2 + 1) \times 100 = 66.7 \text{ percent}$$

$$\text{Specificity} = 182/(182 + 18) \times 100 = 91 \text{ percent}$$

$$\text{Positive predictive value} = 2/(2 + 18) \times 100 = 10 \text{ percent}$$

$$\text{Negative predictive value} = 182/(182 + 1) \times 100 = 99.5 \text{ percent}$$

Where the pretest odds is the prevalence, then:

Probability of disease given a positive test = (prevalence\* X sensitivity) divided by (prevalence X sensitivity) plus ([1 - prevalence] X [1 - specificity])

$$[(3 \times .67) / (3 \times .67) + (1 - 3) \times (1 - .91)] \times 100 = 82 \text{ percent}$$

(\*prevalence of disease is 3)

Table 13-26.

||table:26||

Table 13-27. Commonly Used Symbols and Abbreviations

||table:27||

## Conclusions

Today's healthcare is driven by data. IPs with relevant and accurate data have the opportunity to improve patient outcomes. Once the IP has organized and analyzed the data and selected the appropriate graphic display, the IP should be able to share the data with those in their facility who will use it to drive change.

This chapter is an introduction to the discipline of statistics. For those whose interest has been stimulated to read further, many of the references listed in the Supplemental Resources are excellent resources for the infection preventionist. Statistics provides the infection preventionist with the ability to present credible data that can be transformed into information that can be used by the facility to improve outcomes and quality of care. While many manual mathematical and statistical calculations were demonstrated throughout this chapter, there are numerous computer programs available that will

perform most of the data manipulations covered. There are data mining and artificial intelligence software programs that will collect, organize, analyze, and graph infection prevention surveillance data for the infection preventionist.

Please see Table 13-27 for a list of commonly used symbols and abbreviations used in this chapter.

## Supplemental Resources

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## Process Control Charts

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## Abstract

*Statistical process control should play a central role in all infection prevention programs. Unless one has sufficient training in statistical methods, collecting the correct data and generating appropriate graphics to summarize them can be difficult. Through proper data collection and critical analysis of control charts, the infection preventionist can detect abnormalities in infection rates quickly, which facilitates prompt changes to processes that will yield desirable outcomes.*

## Key Concepts

- Statistical process control is an essential component of quality assurance and performance improvement.
- The principles of statistical process control are used to monitor both processes and outcomes in a systematic and statistically valid manner.
- The elements of statistical process control enable the infection preventionist to generate control charts that present key statistical measurements.
- Control charts can assist the infection preventionist in detecting special cause or common cause variations, which may be helpful for early detection of abnormal events.

## Background

Statistical process control (SPC) is a set of methods that can be used for improving systems, processes, and outcomes. The primary goal of SPC is to recognize and understand "common cause" and "special cause" variations that affect a process. For example, in manufacturing, the weight of 10 of the same mechanical parts will vary slightly from part to part; this is considered common cause variation. The variability is not due to any external factors and will not affect the usability of the part. However, a significant variation may be caused by an external factor leading to special cause variation. This type of variation may affect the parts' usability. A process that exhibits special cause variation is considered to be out of statistical control. Such processes should be investigated to determine the cause of the variation, with the goal of developing interventions to bring the process back into control.

The concept of SPC was first introduced by Walter Shewhart from Bell Labs in 1931 in his book *The Economic Control of Quality of Manufactured Product*.<sup>1</sup> The most notable contribution from this volume is the control chart—a graphical depiction designed to succinctly show the behavior of a process. W. Edward Deming, the famed quality improvement expert, worked with Shewhart on the aforementioned project and was significantly influenced by his study of variation.<sup>2</sup>

The concept of SPC went largely unnoticed until Deming brought it to post-war Japan. In the 1950s, Bonnie Small introduced SPC techniques at the Western Electric Allentown, Pennsylvania, plant to combat manufacturing quality control problems with transistor production. Over time, more than 5,000 control charts were posted around the plant and quality was vastly improved.<sup>3</sup> However, little attention was paid to SPC in the United States until the manufacturing crisis in the 1980s when American appliance, electronic, and car manufacturers sought to improve product quality to compete with Japanese products. SPC was an ideal tool to analyze manufacturing processes.

While SPC was originally designed as a way to monitor manufacturing processes, it eventually found its way into healthcare. Initially, SPC was used to monitor laboratory techniques, which were often analogous to manufacturing processes. Later, SPC was applied to several process areas in healthcare including surgery, primary care, internal medicine, nursing, urology, radiology, and infection prevention and control. Thor and colleagues provide the interested reader with an in-depth review of the literature in which they identify the myriad areas where SPC has been applied to quality improvement in healthcare.<sup>4</sup>

Since the 1980s, SPC has become a standard approach for hospitals to use for quality improvement. In fact, The Joint Commission requires hospitals to engage in continuous quality improvement and use SPC to understand many critical clinical and nonclinical processes.<sup>5</sup>

## Basic Principles

*Statistical control* refers to the stability and predictability of a process over time.<sup>5</sup> If the process is in control, it is operating with only common cause variation and therefore it is possible to predict what all future data points will be. An example of a process is hand hygiene. There are a series of steps to perform hand hygiene that impact the likelihood of disease transmission. If the hand hygiene process is in control, each month the compliance rate is similar (i.e., operating with little variation). Since the compliance rates are all similar, all future rates should also be similar as long as no external events are acting on the hand hygiene process. An external event such as new employees who are unaware of appropriate hand hygiene may increase organism transmission and lead to compliance rates that vary significantly from those previously documented. This is an example of special cause variation; the larger variation in the hand hygiene process is considered out of statistical control.

A critical concept of SPC is that the cause of such variation can be determined and eliminated to bring a process back into control. For instance, suppose a hospital adopts a new disinfectant that is effective against the same pathogens as a previous product, but requires a different dilution. After using the product for several months, the hospital uses SPC and determines that the rate of a particular healthcare-associated infection (HAI) is rising. An investigation into the problem reveals that environmental services staff were incorrectly diluting the new disinfectant. Once the appropriate adjustments are made, the process returns to statistical control (i.e., normal variation).

The central tenet of SPC is that processes are subject to two different kinds of variation: common cause and special cause.<sup>6</sup> As noted previously, common cause variation is inherent to the process whereas special cause is caused by significant changes in or related to the process (such as external factors). An example of common cause would be rates of multidrug-resistant organism infections that vary slightly from month to month under normal circumstances. The variation is not due to any particular unusual issue. On the other hand, an unusual issue may lead to special cause variation. An example of special cause variation is the change in the *Clostridium difficile* infection rate in a facility during an outbreak. This abnormal (high) rate may be due to external influences such as healthcare personnel changes, equipment failure, or poor disinfection practices—essentially any circumstance that is not common, but alters the process when it does occur.

While it is critical to identify and fix special cause variation, it is also important to understand that just because a process may be in statistical control, it is not necessarily acceptable. SPC techniques can be used to identify a process that could benefit from improvement based on its common cause variation. For example, the number of surgical site infections in a trauma center may be stable over time and is therefore under statistical control. However, the trauma physicians may want to reduce the infections by 25 percent in the upcoming year as part of a quality improvement initiative. In this case, nothing abnormal is happening with the rates, but SPC provides a baseline of common cause variation from which to work for process improvement.

Finally, for SPC to be truly useful and not just an academic or management exercise, the source of special cause variation has to be not only identified, but also addressed. Simply noting that a process is

out of statistical control is not enough. Steps must be taken to bring the process back under control by identifying, understanding, and addressing the events causing the problem.

## SPC in Infection Control

### SPC in Infection Prevention and Control

Infection prevention and control departments typically monitor and analyze the rates and frequencies of HAIs such as surgical site infections, central line-associated bloodstream infections (CLABSIs), ventilator-associated events (VAE), catheter-associated urinary tract infections (CAUTI), and those due to epidemiologically important organisms. Analysis usually involves looking at aggregate rates (across the entire hospital) and departmental rates (specific departments or units). Many tools can be used for SPC including control charts, run charts, frequency plots, histograms, and scatter and flow diagrams.<sup>7</sup>

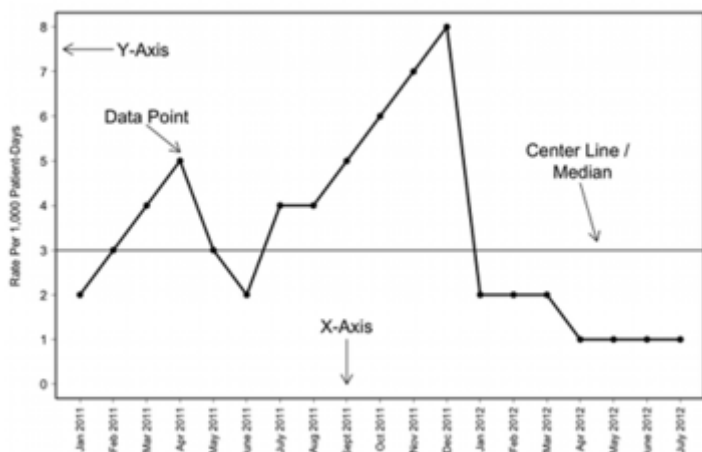
However, the most commonly used are run charts and control charts because they are easiest to interpret for the nonstatistician.

### ANATOMY OF A RUN CHART

Strictly speaking, a run chart is not considered an SPC chart. However, it is convenient when assumptions to construct a control chart (which will be discussed later) are not met, as it can still provide insight into a process.<sup>8</sup> A run chart consists of the following components:

- Center line/median – represents the median of all of the data points. The median is calculated by sorting the rates from smallest to largest and finding the number in the middle. If there is no number in the middle (e.g., even number of data points), the median is calculated by taking the average of the two points in the middle.
- x-axis – represents the time period of interest (days, weeks, months, quarters, years).
- y-axis – represents the scale of the plotted data points (e.g., rate or count of infection).
- Data points – the actual data values (e.g., rates).

For example, suppose an infection preventionist (IP) has collected data on rates of ventilator-associated events (VAEs) each month for a year (Table 14-1). Figure 14-1 illustrates these data on a run chart.



**Figure 14-1.** Anatomy of a run | [View Image](#)



**Figure 14-1.** Anatomy of a run chart.

It is important to note that run charts do not detect the difference between common cause and special cause variation. However, run charts can detect patterns in the data that may suggest problems with the process.<sup>9</sup>

**Table 14-1** Rates of Ventilator-associated Events, January 2011 to July 2012

Month	Rate Per 1,000 Ventilator Days
Jan-11	2

Feb-11	3
Mar-11	4
Apr-11	5
May-11	3
Jun-11	2
Jul-11	4
Aug-11	4
Sep-11	5
Oct-11	6
Nov-11	7
Dec-11	8
Jan-12	2
Feb-12	2
Mar-12	2
Apr-12	1
May-12	1
Jun-12	1
Jul-12	1
Median	3

## DETECTING VARIATION ON A RUN CHART

There are three major rules used to detect variation on a run chart:

1. Seven or more consecutive points on either side of the center line (median).
2. Five or more consecutive points increasing or decreasing.
3. Fourteen or more consecutive points alternating up and down.

Figures 14-2 and 14-3 show these rules graphically.

**Figure 14-2.** Run chart depicting Rules 1 and 2

[View Image](#)



**Figure 14-2.**Run chart depicting Rules 1 and 2.

**Figure 14-3.** Run chart depicting Rule 3

[View Image](#)



**Figure 14-3.** Run chart depicting Rule 3.

We recommend that if your chart has 25 or more data points you should create a control chart instead of a run chart. Control charts allow the IP to detect true special cause and common cause variation. Knowing which type of variation you have is critical for quality assurance, performance improvement,

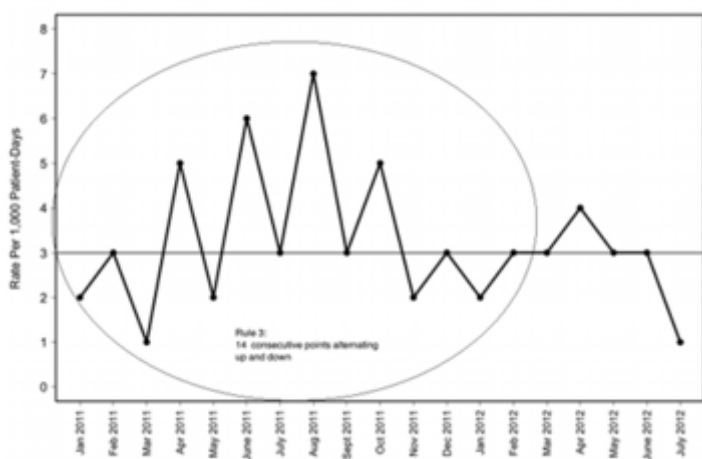
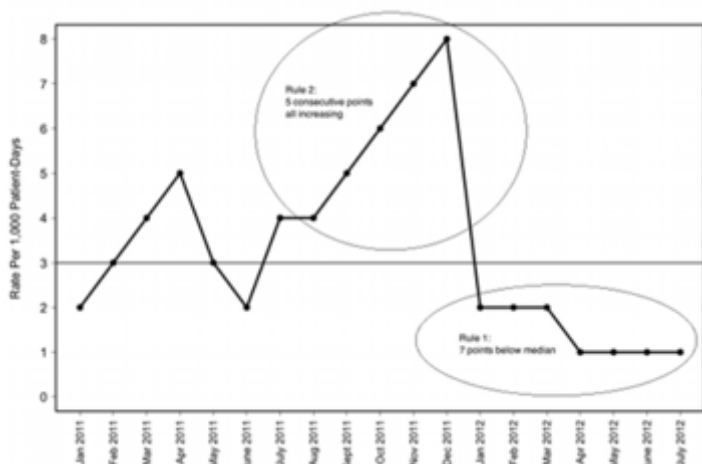
and outbreak identification.

## ANATOMY OF A CONTROL CHART

The primary SPC tool is the control chart, which is a line chart of process data, similar to a run chart except it takes into consideration the significance of the variation as measured by the standard deviation (SD) from the mean. For example, an IP might collect the rate of CLABSI by month for a certain time period as shown in Table 14-2. These rates plotted on an SPC chart can be seen in Figure 14-4.

**Table 14-2** Rates of CLABSI for January 2011 to January 2013

Month	Number of CLABSI	Number of Line Days	Rate Per 1,000 Line Days
Jan-11	1	876	1.1
Feb-11	2	978	2.0
Mar-11	4	879	4.6
Apr-11	2	678	2.9
May-11	3	908	3.3
Jun-11	2	907	2.2
Jul-11	5	987	5.1
Aug-11	4	768	5.2
Sep-11	3	876	3.4
Oct-11	4	978	4.1
Nov-11	5	879	5.7
Dec-11	5	678	7.4
Jan-12	2	908	2.2
Feb-12	3	907	3.3
Mar-12	2	987	2.0
Apr-12	4	768	5.2
May-12	3	876	3.4
Jun-12	4	978	4.1
Jul-12	5	879	5.7

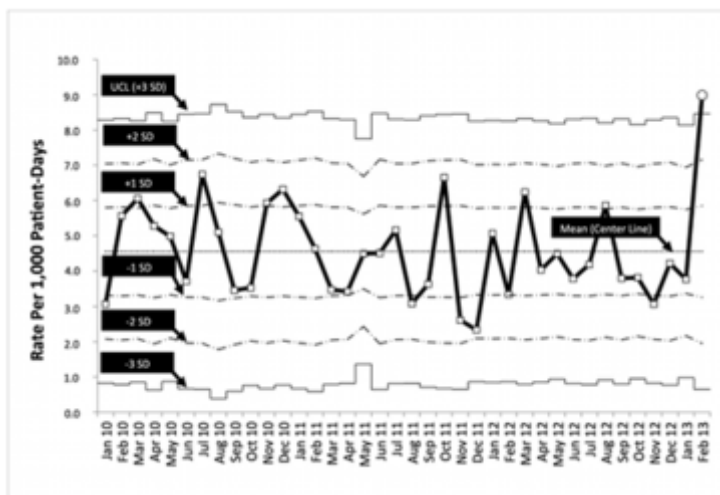




Aug-12	4	678	5.9
Sep-12	3	908	3.3
Oct-12	6	907	6.6
Nov-12	5	987	5.1
Dec-12	4	768	5.2
Jan-13	15	897	16.7

The control chart consists of the following components:

- Center line (CL)/mean – represents the average of data points. This is calculated by summing the monthly rates and dividing by the total number of time periods (months in our example). When a process is in statistical control, the CL depicts the rate we expect to see in the coming months.
- x-axis – represents the time period of interest (days, weeks, months, quarters, years). These time periods may be called subgroups by some authors.
- y-axis – represents the scale of the plotted data points (e.g., rate or count of infection).
- Data points – the actual data values (e.g., rates).
- Upper control limit (UCL)  $+3$  SD from the mean – this line represents high variation above the mean for each data point.
- Lower control limit (LCL)  $-3$  SD from the mean – this line represents high variation below the mean for each data point. This limit is not depicted in Figure 14-4 because a rate cannot be below zero and for this example much of the  $-3$  SD limit would be below zero.
- Other standard deviation indicators ( $+1$ ,  $+2$ ,  $-1$ ,  $-2$ ) – these lines represent other levels of variation above and below the mean for each data point.



**Figure 14-4.** Example control chart for CLABSI using data from Table 14-1 [View Image](#)

**Figure 14-4.** Example control chart for CLABSI using data from Table 14-1.

## DETECTING VARIATION ON A CONTROL CHART

There are eight major rules used to detect special cause variation on a control chart:

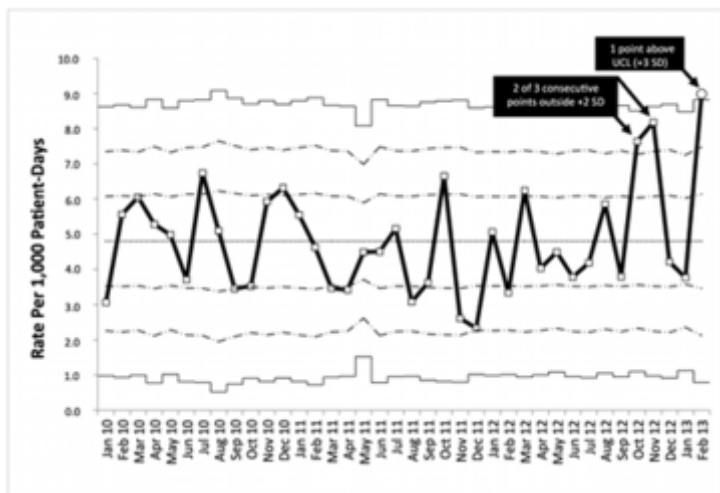
1. Any point above the UCL or below the LCL.
2. One of two points above  $+2$  SD or below  $-2$  SD.
3. Four of five points above  $+1$  SD or below  $-1$  SD.

SD.

4. Eight consecutive points above or below the CL.
5. Six consecutive points increasing or decreasing.
6. Fifteen consecutive points between  $+1$  SD and  $-1$  SD.
7. Fourteen consecutive points alternating up and down.
8. Eight consecutive points above  $+1$  SD and/or below  $-1$  SD.



Figure 14-5 depicts an SPC chart where the first and second rules were violated (hollow square data points), which indicate special cause variation is present. Other methods to detect abnormal variation are available as well. Another common method includes calculating a chi-squared statistic and comparing the observed value for a particular time period to the expected value for that time period. The expected value is calculated similar to that of any chi-squared test but is beyond the scope of this chapter. If the observed value is significantly higher or lower than the expected value, special cause variation is present.



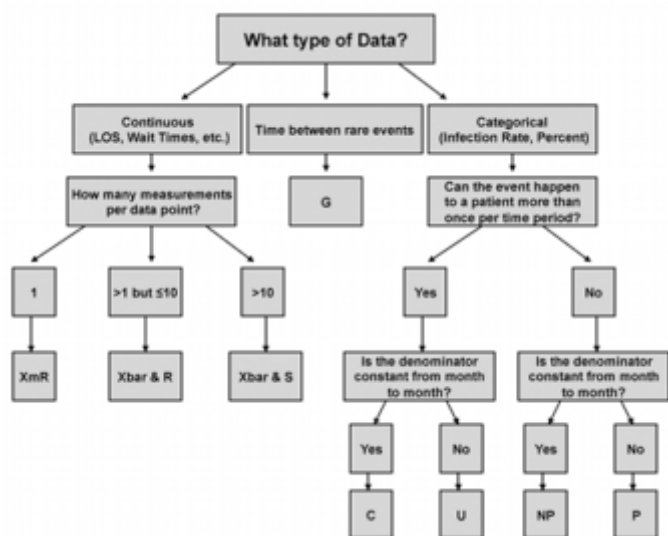
**Figure 14-5.** SPC chart with special cause variation [View Image](#)

**Figure 14-5.** SPC chart with special cause variation.

## CHART TYPES

Since the control limits are calculated slightly differently in different types of charts, it is critical to ensure the correct chart is chosen. Identification of the best chart is dependent on the type of data to be charted. Choosing the correct chart can be difficult as the choice depends on some statistical concepts beyond the scope of this chapter. However, there are

some general “shortcut” rules for choosing the correct chart that have been documented.<sup>8</sup> A flow chart using these shortcut rules is shown in Figure 14-6.



**Figure 14-6.** Choosing the correct control chart type for your data. [View Image](#)

**Figure 14-6.** Choosing the correct control chart type for your data.

The main types of charts used in the field of infection prevention are attributes charts, which are shown on the right side of the diagram depicted in Figure 14-6. The two most commonly used in infection prevention are the u chart and the p chart. These two charts are described more in depth in the following text. For more information regarding the other chart types and how they might be used in your practice, see publications by Benneyan and

Amin.<sup>5,8,10</sup>

## U CHARTS

A u chart should be used when the following three criteria are met:

1. Data are categorical (or count).
2. Data follow a Poisson distribution.

3. A rate is plotted and the denominator of that rate (e.g., number of ventilator days) varies from time period to time period (e.g., month to month).

The shortcut rule for choosing this chart is when the numerator of the rate (e.g., number of infections) can happen more than once to a patient in a single time period. For example, a case of VAE can happen more than once to a patient in one month. If the patient gets VAE due to *Pseudomonas aeruginosa* on the first of the month, the same patient could also get another VAP later in the month due to a different organism. The most common use of a u chart in infection prevention is for plotting rates of device-associated infections when the denominator of the rate changes from month to month.

## P CHARTS

A p chart should be used when the following criteria are met:

1. Data are categorical.
2. Data follow a binomial distribution.
3. A rate is plotted and the denominator of that rate (e.g., number of ventilator days) varies from time period to time period (e.g., month to month).

The shortcut rule for choosing this chart is when the numerator of the rate (e.g., number of infections) can only happen once to a patient in a single time period. IPs performing microbiological surveillance of epidemiologically important organisms often count only the first microbiological isolate of any particular organism for a single patient. So one patient with multiple positive cultures for methicillin-resistant *Staphylococcus aureus* (MRSA) in one month will only be counted one time during that month. In this case, plotting the rate of MRSA per 1,000 patient-days would necessitate a p chart. The most common use of a p chart in infection prevention is for plotting rates of epidemiologically important organisms or infections when the denominator of the rate changes from month to month and only one isolate or infection is counted for each patient during each month.

## ADDITIONAL CONSIDERATIONS

### POSITIVE VERSUS NEGATIVE SPECIAL CAUSE VARIATION

Not all special cause variation is necessarily bad. For example, if we are monitoring rates of *C. difficile* toxin-positive specimens from the microbiology laboratory and the data meet Rule 4 (eight consecutive points fall below the center line), special cause variation has been detected. However, since the rule violated includes data being below the center line, the rate of *C. difficile* toxin-positive specimens is less than we expected to see, which is good. However, if the same rule were violated, except that eight consecutive points were above the center line, the rate of *C. difficile* toxin-positive specimens would have been more than we expected to see, which is bad. Identification of “good” or “bad” special cause variation depends on the data included in the chart.

### NUMBER OF DATA POINTS

At least 25 data points are necessary to construct a proper control chart. With fewer than 25 data points, it is difficult to detect special cause variation. An example is a chart created with 12 months of data on the rate of VAE by month. This chart may not detect special cause variation, and the IP would consider the rate to be in statistical control with no interventions necessary. However, due to the limited number of data points, the control limits cannot be accurately calculated; therefore, special cause variation may not be detectable. In this example the rate of VAE may actually be out of control and an intervention is necessary. It should also be considered that too many data points may lead to false

detection of special cause variation. Because of this, we recommend no more than 50 data points to be included on a control chart. In our previous example, if 100 data points were included and special cause variation was detected, one cannot be certain that the process is truly out of control. This is because the false special cause variation may have been detected due to chance alone and not because the process is truly out of control. This may lead the IP to institute interventions that are not necessary and may not work.

### *CALCULATING THE STANDARD DEVIATION*

A critical issue in the creation of control charts is that of calculating the standard deviation. A common misconception is that the traditional Gaussian formula for standard deviation found in college biostatistics texts and as implemented in standard spreadsheet packages (e.g., Microsoft Excel, Apple Numbers, OpenOffice Calc) is appropriate for calculating control limits in rate or count based charts (e.g.,  $c$ ,  $u$ ,  $p$ ,  $g$ ). In fact, using this formula for these charts could lead to misidentifying special cause variation, which in turn could induce the IP to implement inappropriate interventions or none at all. Each chart has its own formula and software packages designed for SPC use the appropriate formulas for each. Unless you are an expert in SPC, we highly recommend not creating control charts by hand in spreadsheet applications due to the difficulty in calculating the appropriate control limits. Readily available software packages for SPC include, but are not limited to, QIMacros, Minitab, SAS, SPSS, R, and Matlab.

### *CHANGING THE UCL AND LCL TO $\pm 2$ SD*

Special cause variation is due to external influences (e.g., new staff, new disinfectants), and therefore interventions to eliminate special cause variation are focused on identifying and acting on these influences. It has been suggested that changing the UCL and LCL to  $\pm 2$  SD instead of  $\pm 3$  SD would ensure that special cause variation is detected when present. We recommend against this practice because it will lead to false detection of special cause variation. As Benneyan describes, changing the critical limits to 2 SD instead of 3 SD does not change the fact that special cause variation is or is not actually present, it only changes the ability of the chart to detect it.<sup>10</sup> As described previously, false detection can lead to unnecessary implementation of interventions that will not work since there is actually no outside influence present.

### *REMOVING SPECIAL CAUSES*

The primary purpose of a control chart is to identify excessive variation. If the special cause variation indicates high rates of an infection or low rates of compliance, it is critical to intervene and correct the external factor contributing to the variation. This “detect and correct” method also influences the calculations for the control limits in the chart. Whenever special cause variation is corrected, those points must be removed from the chart prior to continued calculation of the center line and the control limits. In our disinfectant example from above, staff were re-educated on the importance of proper dilution and the rates of infection decreased. Therefore, the data points contributing to the special cause variation should be removed from the chart. The rationale behind this relies on the fact that the center line (mean) and control limits (standard deviations) are calculated based on all data points on the chart. In our example, there were special cause variation points indicating that infection rates were too high. Since these points are due to some external influence, we don’t want those points influencing the mean and standard deviation of the points that are due to common causes. Once these points are removed, the control limits and center line should be recalculated to ensure the chart is monitoring the process containing only common cause variation.

## Conclusions

To ensure that infection prevention and control decisions are made using the best information available, the IP must have a firm understanding of the fundamentals of SPC. Specifically, understanding the appropriate methods to construct and interpret  $\bar{u}$  and  $p$  charts is critical for infection prevention teams. IPs must be able to establish a quality and performance monitoring process using SPC that enables infection prevention teams to quickly identify variations in practice or outcomes and determine if and when interventions should be implemented. In addition, SPC provides a tool to assess the impact of those interventions.

## Acknowledgements

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## Risk-Adjusted Comparisons

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### Abstract

*Infection preventionists often seek to make external comparisons when reviewing their hospital's healthcare-associated infection data. While previous methods involved the use of risk-stratified rates, recent methods employed by the Centers for Disease Control and Prevention include the use of a risk-adjusted summary measure called the standardized infection ratio. In utilizing the results of statistical inference, hospitals can determine if their healthcare-associated infection experience, by way of the standardized infection ratio, is different from the national baseline. Such results can help assess success of prevention efforts, as well as prioritize additional prevention activities based on both statistical and practical significance. This chapter focuses on the methods used to calculate the standardized infection ratios and how a hospital can interpret the standardized infection ratio along with statistical evidence.*

### Key Concepts



- Recent improvements upon risk-adjustment methods in the U.S. allow for hospitals to obtain appropriate risk-adjusted summary measures for various healthcare-associated infections by using the standardized infection ratio.
- The standardized infection ratios account for the varying risk in patients for each type of healthcare-associated infection using data reported to the National Healthcare Safety Network as the standard baseline.
- Statistical evidence provides the information needed for a hospital to determine if their healthcare-associated infection experience is different from the national data, as well as the amount of precision on the estimate of their data.

## Background

When communicating their hospital's healthcare-associated infection (HAI) experience to internal committees, infection preventionists (IP) are often asked, "How do we compare to other hospitals in the U.S.? How has our HAI incidence changed over time? What is our hospital's overall rate?" Using annual reports from the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), IPs can compare their hospital's device-associated infection rates to those published by NHSN for each physical patient care location in their hospital. While location-specific or procedure-specific rates are useful tools in assessing HAI experience, the hospital's administration may prefer to receive a single measurement per HAI type for the entire hospital. When this is the case, overall rates are never the best option, as they are not risk-adjusted when pooling data for the hospital as a whole. Instead, the standardized infection ratio (SIR) is a risk-adjusted scalable metric that can be used to achieve the desired goal.

This chapter focuses on the risk adjustment methods employed by NHSN, as well as the use and interpretation of the SIR for three types of HAIs: device-associated infections such as catheter-associated urinary tract infections (CAUTIs), procedure-associated infections such as surgical site infections (SSIs), and laboratory-identified (LabID) events such as *Clostridium difficile* infection (CDI) LabID events.

## Methods

The SIR is a risk-adjusted summary measure used to track HAIs at a national, state, or local level over time. The SIR adjusts for patients of varying risk within each facility. The method of calculating an SIR is similar to the method used to calculate the standardized mortality ratio (SMR), a summary statistic widely used in epidemiology and public health to analyze mortality data. In HAI data analysis, the SIR is a ratio of the actual number of HAIs reported to the predicted number according to the baseline U.S. experience (i.e., NHSN aggregate data are used as the standard population), adjusting for several risk factors that are significantly associated with differences in infection incidence.

**Figure 15-1.**

**Formula 15-1.** 
$$\text{SIR} = \frac{\text{Observed (O)}}{\text{Expected (E)}}$$

Formula15-1.png

[View Image](#)



As a ratio, the numerical value of the SIR conveys either an equivalency between the numerator and denominator,

in which case the SIR is 1, or a difference, in which case the numerator is higher or lower than the



denominator. A SIR greater than 1 indicates that more HAIs were observed than expected, taking into account variation in the types of patients followed; conversely, an SIR less than 1 indicates that fewer HAIs were observed than expected. The term expected can also be interpreted as the predicted number of infections estimated from the baseline data. For the remainder of this chapter, the term "predicted" is used in place of "expected."

So how do we determine the predicted number of HAIs? The number of predicted HAIs is based on a calculation that depends on the type of HAI being measured, as well as the level of risk adjustment performed. Note that, for those who report these data to NHSN, the number of predicted infections, as well as the SIR, is calculated for the hospital. The methods described in this section are intended to provide insight into the calculations performed by NHSN so as to allow for more informed interpretation of a hospital's data. These methods assume use of NHSN data as the source for external comparisons.

## DEVICE-ASSOCIATED INFECTIONS

SIRs for device-associated (DA) infections allow you to summarize your data by more than a single location, adjusting for differences in the incidence of infection among the location types. For example, you could obtain a single CAUTI SIR, adjusting for all locations reported. Similarly, you can obtain one CAUTI SIR for only intensive care units (ICUs) or only non-ICU locations in your facility. Additionally, the CAUTI SIR may be an easier measure to discuss among internal and external stakeholders.

For DA infections, the number predicted is calculated from baseline data, which are published pooled means of infection rates, stratified by patient care location.<sup>1,2</sup> The following example focuses on CAUTI data; however, the same methods can be applied to other DA infections (e.g., central line-associated bloodstream infections).

### EXAMPLE 1: CALCULATING THE NUMBER OF PREDICTED CAUTI

Suppose the infection surveillance team in Hospital A has collected and entered CAUTI data for a single ICU and a single ward location. They would like to calculate the CAUTI SIR but first need to determine the predicted number of infections. There are two locations in this example; however, the methods are the same regardless of the number of locations. The data they have collected appear in Table 15-1.

**Table 15-1** Example CAUTI Data from Hospital A

Location	No. Observed	No. Urinary Catheter Days	Hospital A's CAUTI Rate*	NHSN Baseline Pooled Mean†	No. Predicted CAUTI	SIR (# obs./ # exp.)
ICU	2	789	2.53	2.0	1.578	1.267
Ward	1	364	2.75	1.7	0.619	-----
Overall	3	-	-	-	2.197	1.365

\*per 1,000 urinary catheter days.

†example data; for teaching purposes only.

Using Formula 15-2, the number of predicted CAUTIs for each location was calculated:

**Figure 15-2.** Formula15-2.png

[View Image](#)



**Formula 15-2.**

$$\# \text{ predicted CAUTI} = \text{urinary catheter days} \times \frac{\text{NHSN Pooled Mean}}{1000}$$

calculated for each location, the SIRs can also be calculated using Formula 15-1, either for each location separately, among a subset of locations, or for all locations combined. Notice that in Table 15-1, the "overall" SIR is calculated by taking the total number of observed CAUTIs and dividing that by the total number of predicted CAUTIs; it is *not* the sum of the individual location-specific SIRs.

**Overall SIR =**

$$\frac{2 \text{ observed CAUTI in ICU} + 1 \text{ observed CAUTI in Ward}}{1.578 \text{ predicted CAUTI in ICU} + 0.619 \text{ predicted CAUTI in Ward}} = \frac{3}{2.197} = 1.365$$

adjustment methods. In this case, the number of predicted SSIs is the sum of risk for each individual procedure record. This method of risk adjustment allows for the group of risk factors to be procedure-specific and each risk factor's contribution will vary according to its significant association with risk.<sup>3</sup>

**EXAMPLE 2: CALCULATING THE NUMBER OF PREDICTED SSI USING LOGISTIC REGRESSION**

This table lists the risk factors found to be statistically significant for a particular NHSN operative procedure category. Note that each risk factor's contribution varies as represented by the parameter estimate for that risk factor.

The parameter estimates in Table 15-2 can be plugged into **Formula 15-3**:

$$\begin{aligned} \text{logit}(\hat{p}) &= \alpha + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 \\ &= -5.448 + 0.520(\text{Age} \leq 44^*) + 0.425(\text{ASA } 3/4/5^*) + \\ &\quad 0.501(\text{Duration} > 100^*) + 1.069(\text{Medical school affiliation}^*) \end{aligned}$$

Factor	Parameter Estimate*
Intercept	-5.448
Age ( $\leq 44$ vs. $> 44$ )	0.520
ASA (3/4/5 vs. 1/2)	0.425
Duration ( $> 100$ vs. $\leq 100$ )	0.501
Medical school affiliation (Y vs. N)	1.069

The estimated probability of SSI for each individual procedure is calculated using the logistic regression model above, where:

**For example:**

# predicted CAUTI in the ICU = 789 urinary catheter days

$$\times; (2.0/1,000) = 1.578$$

Once the number of predicted infections is

**Figure 15-3.** FormulaSIR.png[View Image](#)**PROCEDURE-ASSOCIATED INFECTIONS**

For SSIs, the number of predicted infections is based on rates that are calculated as a result of logistic regression models utilizing CDC risk

**Figure 15-4.** Fig 15-3[View Image](#)

\*For these risk factors, if present = 1; if not = 0.

**Table 15-2** Example Risk Factors for an Unspecified Operative Procedure Category

$\alpha$ = parameter estimate for the intercept

$\beta_i$ = parameter estimate for the designated risk factor  $i$

$X_i$ = value indicating presence or absence of designated risk factor  $i$

Table 15-3 represents a partial list of 100 hypothetical patients who have undergone this particular procedure, and the risk factors present for each. Using the risk model in Formula 15-3, the estimated probability of SSI for Patient 1 in Table 15-3 can be calculated as:

$$\text{logit}(\hat{p}) = -5.448 + 0.520(1) + 0.425(1) + 0.501(1) + 1.069(1) = -2.934$$

$$\text{Solve for } \hat{p}: \hat{p} = e^{\text{logit}(\hat{p})} / (1 + e^{\text{logit}(\hat{p})})$$

$$\hat{p} = e^{-2.934} / 1 + e^{-2.934} = 0.050 \text{ probability of SSI for Patient 1}$$

**Figure 15-5.** Formula 15-3

[View Image](#)



Note that this can also be interpreted as a 5.0 percent risk of SSI for Patient 1.

\*Example data; for teaching purposes only.

The estimated probability of SSI is calculated for each patient undergoing the selected

procedure. Thus, the predicted number of SSIs is obtained by summing all of the estimated probabilities of SSI for each patient among the group of patients or procedures of interest.

Similar to the SIR calculations for CAUTI, SSI SIRs can be calculated at a granular level (e.g., by procedure category) or at an overall level (e.g., all procedure categories combined for the entire hospital). Note, however, that a different set of risk factors, with different parameter estimates, exist for each operative procedure category as described by Mu and colleagues.<sup>3</sup>

**Table 15-3** Example Patients Undergoing Unspecified Operative Procedure

Patient	Age	Duration (min)	ASA	Medical School	SSI	Probability of SSI
1	40	117	4	Y	0	0.050
2	53	95	2	N	0	0.004
3	30	107	2	Y	1	0.033
.	.	.	.	.	.	.
.	.	.	.	.	.	.
.	.	.	.	.	.	.
100	37	128	4	Y	1	0.050

## LABORATORY IDENTIFIED EVENTS

Methicillin-resistant *Staphylococcus aureus* (MRSA) and CDI LabID events are a third HAI category for which SIRs provide a risk-adjusted summary measure. The risk adjustment for these events uses negative binomial regression that is better suited for summarized person-time surveillance data. This method allows for the calculation of SIRs from summarized surveillance data and is based on inpatient facility-wide (FacWideIn) surveillance of these event types.<sup>4,5</sup> An example can help explain this method of risk adjustment.

### EXAMPLE 3: CALCULATING THE PREDICTED NUMBER OF CDI LABID EVENTS

Suppose Hospital A is a 150-bed acute care hospital that serves as teaching hospital for a nearby medical school (i.e., the hospital has an undergraduate medical school affiliation). This hospital has been performing FacWideIn CDI LabID surveillance for one calendar quarter. This hospital's community-onset (CO) CDI prevalence rate for this quarter is 0.36. They reported 10,934 CDI patient days for the quarter, and their laboratory uses the nucleic acid amplification test (NAAT) to detect CDI infections. This hospital identified seven incident, healthcare facility-onset (HO) CDI LabID events during this same time period.

The general format for this negative binomial regression model used in this analysis is presented as Formula 15-4.

**Formula 15-4:** Number of predicted LabID events  

$$= e^{(\beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots)} \times \text{patient days}$$

**Figure 15-6.** Formula 15-4

[View Image](#)



The risk model used for CDI LabID events appears in Table 15-4. By applying Formula 15-4 to the risk model, we can calculate the

number of predicted incident HO CDI LabID events for this time period.

Using Formula 15-4 and the parameter estimates in Table 15-4, Hospital A could calculate the number of predicted infections for their hospital as shown here:

Number of predicted incident HO CDI LabID events =  
**exp** [−7.8983

+ 0.3850(CDI test type = NAAT\*)  
 + 0.1606(CDI test type = EIA\*)  
 + 0.3338(CO CDI prevalence rate)  
 + 0.2164(bedsize > 245\*)  
 + 0.0935(bedsize = 101-245 beds\*)  
 + 0.1870(medical school affiliation = major\*)  
 + 0.0918(medical school affiliation = graduate\*)]  
 &times; CDI patient days

\*For these risk factors, if present = 1; if not = 0

**Table 15-4** Model to Predict Healthcare Facility-onset CDI LabID Events, NHSN, 2010-2011\*

Effect	Parameter Estimate
Intercept	−7.8983
CDI Test Type (NAAT vs. non-NAAT/EIA others)	0.3850
CDI Test Type (EIA vs. non-NAAT/EIA others)	0.1606
CO Admission prevalence rate (continuous)†	0.3338
Facility Bedsize (> 245 vs. ≤ 100)	0.2164
Facility Bedsize (101-245 vs. ≤ 100)	0.0935
Medical School Affiliation (Major teaching vs. Undergraduate/Nonteaching)	0.1870
Medical School Affiliation (Graduate vs. Undergraduate/Nonteaching)	0.0918

\*Adapted from Dudeck, et al.<sup>4</sup>

†Number of community-onset CDI LabID events

$$\frac{\text{Number of community-onset CDI LabID events}}{\text{Number of admissions to the facility}} \times 100$$

**exp** [−7.8983

+ 0.3850(1)

+ 0.1606(0)

+ 0.3338(0.36)

+ 0.2164(0)

+ 0.0935(1)

+ 0.1870(0)

+ 0.0918(0)]**x 10,934**

**= 7.39 predicted incident HO CDI LabID events**

Notice that for those risk factors that were not present in Hospital A (e.g., EIA test type, major or graduate medical school affiliation), the parameter estimates were multiplied by 0, thereby allowing those risk factors to dropout of the calculation.

By applying Formula 15-1, we can calculate Hospital A's quarterly CDI LabID SIR as:

**SIR =**

$$\frac{7 \text{ observed incident HO CDI LabID Events}}{7.39 \text{ predicted incident HO CDI LabID events}} = 0.947$$

**Figure 15-7.** Hospital A's quarterly CDI LabID SIR

[View Image](#)



## Use and Interpretation

While the SIR is a powerful risk-adjusted summary measure, it reflects a single estimate comprised of both numerator (i.e., number observed) and denominator (i.e., number predicted) elements that should be considered when interpreting this metric, especially if it is being used for decision making within an institution.

Here are several examples that demonstrate how two hospitals could interpret their SIRs, including the use of statistical tests to make external comparisons.

**Table 15-5** Example SIRs for Hospital A, during Quarter 1

HAI	No. Observed	No. Predicted	SIR	pValue	95% CI
CAUTI	3	2.197	1.365	0.3765	0.282, 3.991
SSI	24	14.196	1.691	0.011	1.083, 2.516
CDI LabID	7	7.39	0.947	0.5408	0.381, 1.952

**EXAMPLE 4:**

It is time for the IP at Hospital A to present SIRs for the first quarter for CAUTI, SSI, and CDI LabID data. She has generated SIRs for each HAI type from the NHSN application. Table 15-5 is a summary of Hospital A's data for this time period.

First, interpret the CAUTI SIR from Table 15-5. During the first quarter, Hospital A identified three CAUTIs. Based on national baseline data, 2.197 CAUTIs were predicted given the number of urinary catheter days in the ward and ICU during this same time period. This yields an SIR of 1.365, indicating that Hospital A observed approximately 36 percent more infections than would be predicted based on national data.

Next, the *p*value and 95 percent confidence interval (95 percent CI) provide statistical evidence used to draw conclusions. When using the NHSN application to obtain SIRs, the *p*value and 95 percent CI are automatically calculated. Both the *p*value and 95 percent CI are results of statistical inference that, in this case, compare the facility's SIR to the nominal value of 1. Remember, the SIR is a ratio of observed to predicted; therefore, the value of 1 indicates the facility observed the exact number of infections that were predicted.

The *p*value is, in simplest terms, the probability of attaining the reported SIR based entirely on the assumption that the facility's HAI experience is no different than what would be predicted from the national baseline data. In other words, how rare is the reported SIR based on chance alone if we assume the facility has the same HAI experience as that determined by the baseline data? A convenient cut-point for indicating the point of being too rare that is widely used and accepted in the literature is  $p \leq 0.05$ . When the *p*value is  $\leq 0.05$ , we can conclude that it is too rare for the reported SIR to be equal to 1 by chance alone (i.e., a less than 5 percent chance) and, therefore, it is statistically significantly different than 1. On the other hand, when using this convenient cut-point and the *p*value is  $> 0.05$ , this indicates that the result is more likely to have occurred by chance and not considered as rare; thus, we would conclude that the SIR is not significantly different than 1.

The 95 percent CI is an interval within which there is a high degree of confidence that it includes the true SIR. The upper and lower limits can be used to determine both the statistical significance testing result and the precision of the SIR. The precision allows us to assess variability of an estimated SIR. The more narrow the width of the 95 percent CI the more precise the SIR that indicates greater stability and raises confidence in our estimation of the reported SIR. How do we know if the 95 percent CI indicates the reported SIR is significantly different than 1? For SIRs, we look to see if the 95 percent CI includes 1, or rather, we look to see if the lower and upper bound are either both less than 1 or both greater than 1. Figure 15-1 illustrates fictitious 95 percent CIs and their interpretations.

Note that when both bounds are either less than 1 or both are greater than 1, we can determine that the SIR is statistically significantly different than 1. However, if the lower bound is *less than* 1 and the upper bound is *greater than* 1, then the SIR is *not* statistically significantly different than 1 because the 95 percent CI includes 1. Additionally, we could look at the CI width in order to better understand the amount of precision around the reported SIR. Again, a narrow CI indicates more precision and stability, whereas a wider 95 percent CI implies less precision indicating greater variation around the estimated or reported SIR.

### Figure 15-8.

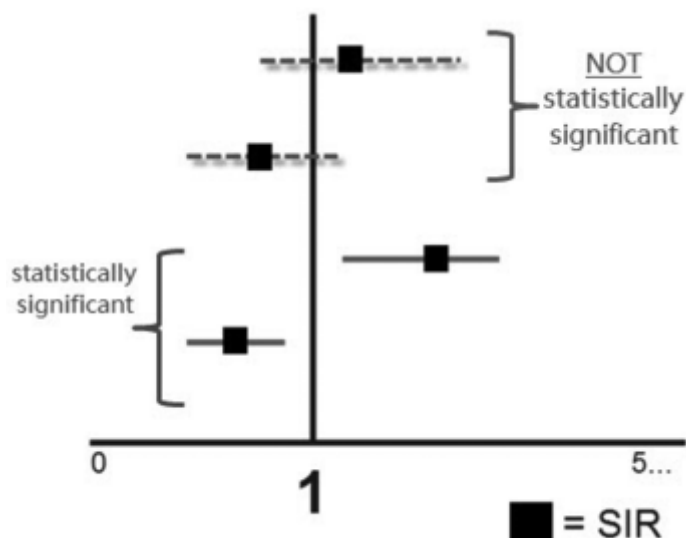
Illustration of 95 percent CIs.

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Going back to the example CAUTI SIRs in Table 15-5, we can conclude that based on the *p*value and 95 percent CI there is no statistical evidence to indicate that the CAUTI SIR is different than 1. Or, we could also say that based on statistical evidence there were no more CAUTIs observed than what were predicted based on the national baseline data. Notice that the *p*value (0.3765) and 95 percent CI (0.282, 3.991) lead us to the same conclusion: no statistical significance. However, the practical





significance of observing more infections than predicted heightens the necessity for improved prevention of this HAI in Hospital A.

**Table 15-6** Example SIRs for Hospital B, during Quarter 1

HAI	No. Observed	No. Predicted	SIR	pValue	95% CI
CAUTI	2	0.763	—	—	—
SSI	4	2.387	1.676	0.2186	(0.8, 2.5)
CDI LabID	1	0.962	—	—	—

IP for Hospital A also should prepare to answer questions from their committee, such as: Where did the infections occur? Were there any months for which there were no infections? To which procedure categories are the SSIs attributed? If the SIRs are not statistically significant, does this mean that focus and attention should be turned away from this type of HAI? While we do not have all of the information available to us in our example, we could certainly begin to answer some of these questions, continuing with the CAUTI SIR.

Interpreting the SIR and the statistical results are just the beginning of the interpretation. The

**Where did the infections occur?** Referring back to Table 15-1, we can see that the ICU made the larger contribution to Hospital A's CAUTI SIR, as two of the three CAUTIs identified in the first quarter occurred in the ICU. In addition, the number of urinary catheter days was more than twice than those in the ward, which contributes largely to the overall number of predicted CAUTI for the hospital. Reviewing this level of detail can aid the IP and their hospital in determining which patient care areas may be in greater need of CAUTI prevention efforts and education.

**If the SIRs are not statistically significant, does this mean we do not need to focus our attention on that type of HAI?** Not necessarily. This is really a more subjective question and depends on many factors, including what the hospital is trying to measure and what prevention and reduction goals have been set. In other words, there may be instances when practical significance takes precedence over statistical significance. For instance, if a unit or facility is very large with many patient days, device days, or surgical procedures of a given type, an SIR may not be (statistically speaking) significantly higher than 1 and yet working to reduce the SIR to get at or below 1 could prevent many infections and patient harm.

### EXAMPLE 5:

Hospital B is a small, 50-bed hospital that has also been performing CAUTI, SSI, and CDI LabID surveillance. The IP at Hospital B has generated SIRs from NHSN for the first quarter, as listed in Table 15-6.

Since Hospital B is a much smaller hospital than hospital A, the number of patients at risk (e.g., patients with urinary catheters, patients undergoing a procedure) is much less; and therefore, fewer infections are predicted to occur. Notice that in Table 15-6, SIRs are not calculated for CAUTI and CDI LabID; this is because less than one infection was predicted to occur for each. When less than 1 infection is



predicted to occur, NHSN does not calculate the SIR or statistical inference results in order to help enforce a minimum precision criterion. Remember, the methods for calculating the number of predicted infections is dependent on national baseline data, as well as the hospital's data. Therefore, when estimating the SIR for infections of lower incidence and/or lower exposure or risk of patients in the hospital, the number of predicted infections would be lower and, in some cases, not even one infection is predicted to occur.

What are the options for the IP at Hospital B? Should they only report on the SSI data because that is the only HAI for which an SIR was calculated? Although the IP does not have SIRs for CAUTI and CDI LabID, they could focus on the practical significance of the data. For example, two CAUTIs were identified in Hospital B and based on the type of unit and the national baseline data, less than one was predicted to occur. Therefore, the fact that two were identified could be cause for concern for this small hospital. The IP may seek to investigate this issue further—were there changes in staff, or were there changes in the devices used or how they were maintained? Has this been a trend over the past few quarters? The IP may closely monitor device use and maintenance over the coming months to determine if there is an upward trend in CAUTI incidence that has not been previously observed.

Another option in analyzing and interpreting the data in Hospital B is to look at the data for larger time periods (e.g., semiannual, annual). Doing this would allow for greater precision for the summarized measurement of each HAI type in this hospital. The IP could choose to combine this with more timely assessment of HAI incidence by using rates on a monthly or quarterly basis.

Interpreting the SSI SIR for Hospital B is similar to the CAUTI interpretation for Hospital A: During the first quarter, four SSIs were identified. Based on the types of procedures performed and the national baseline data, 2.387 SSIs were predicted. This yields an SIR of 1.676 and the statistical evidence indicates that this SIR is *not* statistically significantly different from 1.

However, let us look closer at the SSI SIRs for both Hospital A (Table 15-5) and Hospital B (Table 15-6). Notice that both have similar SIRs: 1.691 in Hospital A, and 1.676 in Hospital B. Yet, the conclusions from the statistical evidence are different. Why is that? The answer calls for taking precision into account. As the higher volume hospital, Hospital A performed more procedures and thus predicted more SSIs to occur (# predicted = 14.196), whereas Hospital B performed fewer procedures and predicted far fewer SSIs (# predicted = 2.387). In addition to the procedure volume, keep in mind that the risk calculated for each patient undergoing these procedures, as well as the types of procedures, could differ between the two hospitals, which would factor into the predicted SSI count. Also notice that the 95 percent CI for Hospital A's SSI SIR is *more narrow* than the same for Hospital B, indicating greater precision around Hospital A's estimated SIR.

## Conclusions

Many IPs and hospital administrators long have preferred risk-adjusted rates to other summary HAI measures as a means for describing HAI incidence in the hospital and for comparisons between their hospital and national HAI data. However, one important limitation to using rates is that there may be many patient care locations on which to report, in which case a potentially diverse and large set of rates is produced that is difficult to summarize for purposes of internal quality evaluation and external comparisons. This potentially large set of rates is unwieldy, and it is methodologically unsound to simply pool multiple rates to provide a single measure of incidence over multiple strata. In the case of SSIs and LabID event data, the risk adjustment afforded by models that include either continuous variables or several categorical variables with multiple categories requires a large number of tables to display all the

comparator rates across the different risk strata. By contrast, the SIR is a methodologically sound method for summarizing a hospital's HAI incidence for specific HAI types across multiple strata and comparing the hospital's experience with what is predicted from national data.

Risk-stratified rates can, and should, continue to be utilized as they can provide insight into the hospital's location- or procedure-specific trends over time. However, SIRs provide acceptable, risk-adjusted measurement of HAIs that can be summarized to communicate the HAI experience of the hospital, state, or nation as a whole. The risk-adjustment methodologies employed by the CDC's NHSN enable hospitals to make external comparisons using a single metric for each type of HAI, measuring how many HAIs they identified compared to what the national data would predict for that hospital, based on the types of patients receiving care in that type of institution. Further, statistical inference results can be produced with SIRs to interpret any statistical evidence of difference between the hospital's experience and the national comparative data.

IPs who use SIRs in their hospital should also consider the practical significance in the measurement, as well as additional information that can aid in the interpretation of the data. The SIRs can be used to prioritize prevention activities within the hospital for each HAI type, as well as specific patient care areas and procedure types. Such decisions can be made with the desire to observe fewer infections than predicted (i.e., SIRs less than 1) in an effort to improve patient care. Factors such as trends related to the incidence of HAIs, implementation of new devices and/or prevention practices, or even observations related to change in staff can contribute to the use and interpretation of SIRs.

## Supplemental Resources

NHSN Website: <http://www.cdc.gov/nhsn/index.html>

NHSN Annual SIR Report: <http://www.cdc.gov/hai/national-annual-sir/index.html>

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## Quality Concepts

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### Abstract

*There are many approaches and strategies an individual or organization can use to demonstrate quality improvement. An infection preventionist often requires a toolbox approach to performance improvement in order to determine the best method to achieve a desired outcome. The infection preventionist will plan, implement, and evaluate strategies that ensure compliance with evidence-based practices and accreditation standards, and improve patient safety. An effective prevention and control program encompasses responsibility, collaboration, consultation, and a broad vision to look at community risks and resources. Infection preventionists must communicate evidence-based guidelines to leaders and staff within an organization and integrate the guidelines into a comprehensive program. A multidisciplinary approach helps the infection preventionist develop an organizationwide program that reduces the risk of infection to patients, families, and others and protects the community.*

### Key Concepts

- Healthcare quality improvement uses interdisciplinary teams to deploy changes and improvements. A quality-focused culture values the knowledge, skills, and expertise of frontline workers and other professionals to use innovation, scientific methods, and effective change management approaches to improve healthcare services and ensure patient safety.
- Infection prevention places upon the infection preventionist the responsibility to perform broad continuous quality improvement studies using systematic programs and tools and to determine outcomes.
- Tools for a quality toolbox include elements such as gap analysis, root cause analysis, failure mode effects analysis, assessment of strengths and weaknesses in the program and control charts, as well as checklists and guiding documents.

- Performance improvement is an ongoing continuous cycle that focuses on patient clinical outcomes, customer satisfaction, and service. Program interventions determine effectiveness and efficiency and can determine whether proactive approaches or retrospective analysis can further improve program quality.

## Background

Since the end of World War II, W. Edwards Deming's business philosophy, summarized in his famous 14 Points, has inspired significant changes among a number of leading U.S. companies that strive to remain competitive in today's economic environment. Businesses and healthcare companies often embrace a performance improvement model such as the Plan, Do, Study, Act (PDSA) cycle. This methodology has proven effective to create a constant purpose toward change. The PDSA cycle, championed by Deming, is an iterative process that is repeated again and again for continuous improvement.<sup>1</sup>

The planning concepts, which follow Deming's model, focus on meeting customers' needs and expectations; on business leaders implementing the mission, vision, and values of an organization; and on defining measurable outcomes. Planning activities consist of activities such as process mapping or conducting a gap analysis. The plan is executed in the Do cycle to accept or reject the project hypothesis. In the Study cycle, clinicians conduct a root cause analysis, or a failure mode effect analysis (FMEA), to systematically identify process failures and prioritize change. The Study also includes an analysis of actions such as developing pilot programs and conducting strategic planning activities that focus an organization's efforts to improve quality. The Act phase consists of instituting strategies and measuring the effect of the action on the project. Act also includes revision of strategies if the strategy does not meet the outcome goal.

Quality professionals refer to the relationship between variation and cost as quality waste. Examples of measurement tools include check sheets, run charts, histograms, Pareto charts, and statistical process control charts. Descriptive statistics along with control charts help to understand and measure the health of the process. Measuring outcomes requires a good understanding of data and data variances in order to determine sustainability of process improvements.

## Basic Principles

### QUALITY INFECTION PREVENTION AND CONTROL PROGRAMS

In 1996, the Institute of Medicine (IOM) launched a concerted effort to improve the nation's healthcare quality. The first phase of the IOM's effort consisted of outlining the serious nature of the quality problem, concluding that "the burden of harm conveyed by the collective impact of all of our health care quality problems is staggering."<sup>2</sup> The second phase of the effort consisted of how to transform the healthcare system and policy environment to close the gap between good quality and what actually exists in practice. The IOM released monumental reports: *To Err Is Human: Building a Safer Health System*<sup>2</sup> and *Crossing the Quality Chasm: A New Health System for the 21st Century*<sup>3</sup> that substantiated reform and addressed the ills of the healthcare system. These reports present a future state of the health system and discuss necessary changes at the environmental level, the organizational level, and at the level of communication between clinicians and patients. *To Err Is Human* focused on the number of Americans who die each year because of medical error and brought to the forefront the issue of



patient safety. The report described six aims of care: safety, effectiveness, patient centeredness, timeliness, efficiency, and equity. A healthcare organization's infection prevention and control program encompasses all of these aims and deals with many broad quality issues, such as community outbreaks and environmental cleanliness, policy and procedure development (organizational consistency), and staff education (communication).

Effective infection prevention and control programs focus on conducting surveillance to determine the incidence of healthcare-associated infections (HAIs) and design reliable interventions to reduce and eliminate pathogen transmission. Staff, clinicians, and visitor education must focus on performing proper hand hygiene, using appropriate personal protective equipment, instituting isolation procedures, identifying multidrug-resistant organisms, providing appropriate antibiotic prophylaxis, and performing proper cleaning practices—all in an effort to prevent HAIs. Measuring how a facility or organization controls or complies with policies; documents results of observational audits; performs root cause analyses; reports individual physician or unit rates; and benchmarks the organization's infection rate against community, state, and national averages provide the basis for a robust performance improvement program.

Improving the quality of the patient's stay concentrates on preventing a patient's exposure to infectious agents. With any quality improvement initiative, organizations should generate baseline data and measure results both pre- and post-implementation of improvement strategies. Infection preventionists (IPs) have shifted from a reactive style of monitoring elements of a program to a proactive, preventive approach. The IP is responsible for performing broad continuous quality improvement studies using systematic programs and tools. For example, IPs and others may monitor—through real time audits—antibiotic prophylaxis before surgery, intraoperatively, and postoperatively to determine whether a surgeon and the operating room team meet "best practice" quality guidelines to prevent post-operative infections in patients.

## Tools for a Quality Toolbox

### THE STRATEGIC PLAN

Strategic plans<sup>4</sup>determine the direction an organization will go in the future and what the organization must do in order to reach the goal, mission, or vision. Strategic planning involves several important steps: (1) an analysis of the organization; (2) forming conclusions about what an organization must do as a result of issues facing the organization; and (3) action planning. Action plans determine what tactic the organization will use to accomplish goals, who will take responsibility to carry out the action, the time line of action, and resources and evaluation criteria.<sup>4</sup>According to The Joint Commission (TJC), a comprehensive infection prevention and control program must have a detailed strategic plan that:

1. Prioritizes the identified risks for acquiring and transmitting infections.
2. Sets goals that include limiting (a) unprotected exposure to pathogens; (b) the transmission of infections associated with procedure; and (c) the transmission of infections associated with the use of medical equipment, devices, and supplies.
3. Describes activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.
4. Describes the process to evaluate efficacy of the plan.

Periodically throughout the course of a year, the prevention team reviews and may revise the strategic plan based on issues, outbreaks, or investigative findings that arise within the facility using specific,

measurable, attainable, realistic, time-bound (SMART) goals.

## PERFORMANCE IMPROVEMENT TEAMS<sup>5</sup>

Multidisciplinary teams are a valuable tool in deploying a quality-focused culture or process. Successful teams increase problem solving and efficiency, raise morale and productivity, use integrative rather than imposed solutions, increase acceptance of the solution, and tap the potential in people and their fundamental knowledge of the process. They also align efforts with the mission, vision, and values of the organization and identify customers and expectations. Deming's contribution was to view the organization as a system, a network of interdependent components working together with a common goal.

A project team or committee is composed of subject matter experts who do the work. The team leader retains the management responsibility, has expertise in the process under study, and regularly communicates with the guidance team. A project team facilitator is a technical advisor, teacher, and expert on team process, although not necessarily on the process under review or study. Team members have the fundamental knowledge of the process under study and are usually frontline employees. Brainstorming helps existing or newly organized teams define the project or process they are assigned to improve and enhances their problem-solving potential by encouraging creative and innovative thinking.

Some healthcare organizations create guidance teams that may be incorporated into an infection prevention and control committee that is responsible for surveillance oversight, such as a hand hygiene team that conducts observations of hand hygiene practices. The performance improvement team selects the process or project they wish to improve and provides a clear mission statement for team members and a detailed description of desired outcomes. A quality action team may create subteams, such as a project team that works to mobilize needed resources. Senior leadership acts as a guidance team that removes institutional barriers and speeds implementation of the changes recommended.

Interdisciplinary teams or committees establish group norms and logistical considerations such as meeting places and times, assignments, completion dates, or time frames. Performance without clear objectives and role definitions may lack commitment or full attendance by team members. They may have a leader who does not explore a variety of strategic actions or may experience confusion about roles, time lines, and outcome initiatives. The use of team charters help ground the team in a collective mission and team leaders should structure meetings to maximize productivity, give credit for new ideas, and reward and recognize positive outcomes and behaviors. Most importantly, teams prove effective and accomplish work with the support of senior organizational leaders and managers. Senior leadership creates the quality culture and requires team members to report and discuss their valuable learning experience.

Occasionally, teams or committee members are in conflict about what the team should accomplish. Conflict is *not necessarily* a result of people being right or wrong; rather, it can arise when people have strengths in different areas or when individuals defend a value position, rather than concentrating on objective facts. Conflict can be productive and foster creativity, but the team facilitator must be able to negotiate, arbitrate, counsel, and resolve conflict.

**Table 16-1** Sample GAP Analyses

Duty Number	Description	Evidence	Gap/Compliance/Action
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1	To protect patients, staff, and others from HAIs	Joint Commission standard IP.01.05.01 2009 EP: 7	Yes
2	Assess risks of acquiring HAIs and take action to reduce or control such risks	Joint Commission standard IP IP.01.03.01 2009 EP: 5	No  Review risk assessment quarterly and communicate to infection prevention program committee

## GAP ANALYSIS

Business and quality professionals describe a gap analysis as a technique to compare best practices with the current processes and determine the steps to take to move from a current state to a desired future state.<sup>6</sup> A gap analysis begins with (1) listing characteristic factors, such as attributes,

competencies, or performance levels of the present situation (what is); (2) listing factors required to achieve future objectives (what should be); and (3) identifying the highlights or "gaps" that exist within the process and that must be filled in order to meet a goal or achieve standard compliance. Literature also refers to a gap analysis as a need-gap analysis, needs analysis, and needs assessment.

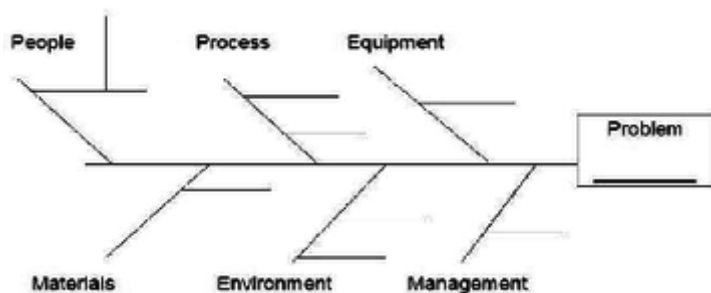
A gap analysis tool can help individuals performing the analysis with identifying gaps that exist between a new standard and the organization's processes. Once the organization knows exactly where the gaps are, the organization can take steps to fill the gaps. By using this approach, organizations can measure standard compliance and improve the overall effectiveness and quality of the infection prevention and control program. Table 16-1 provides sample information in a gap analysis.

## ROOT CAUSE ANALYSIS

The root cause analysis (RCA) process takes a retrospective look at adverse outcomes and determines what happened, why it happened, and what an organization can do to prevent the situation from recurring.<sup>7,8</sup> Risk managers and patient safety experts use the RCA widely to investigate major incidents, sentinel events, or errors in healthcare delivery. The RCA process avoids individual blame, considers human factors engineering, and analyzes redesign for a safer system. When conducting RCA, a multidisciplinary team discovers basic and proximate causes for what happened. The team includes frontline staff, and individuals most familiar with the situation dig deep into the process, asking why something happens at each level of cause and effect. The entire RCA process identifies changes to a particular process or system that improves safety or reduces process error. A thorough RCA determines: (1) human and other factors; (2) the process or system involved; (3) underlying causes and effects of the process; and (4) the risks and potential contributions to failure or adverse results. A credible RCA must involve leaders of the organization and incorporate into the process evidence-based literature that pertains to systems or practices. The RCA does have limitations, such as (1) the team must delve deep enough into the adverse cause of the problem in order to determine process change; (2) the RCA may be expensive, time-consuming, and labor intensive; and (3) team members may require training on the techniques, goals, and outcomes before participating in the RCA.

An RCA team collects data through structured interviews, document reviews, and field observations to determine exactly what happened. Data are analyzed to identify latent failures in sequence. Usually a team categorizes contributing factors according to clinical practice; regulatory, policy, or accreditation factors; operational or management factors; and staff tasks and patient characteristics. A tool called a fishbone diagram (or Ishikawa) may help display the process of identifying contributing factor categories.

Figure 16-1 shows the elements of an Ishikawa diagram using a specific example for IPs. This diagram helped identify elements involved in preventing a central line-associated bloodstream infection and identified various compartments of responsibility and accountability as part of the improvement process. These areas of responsibility can often be identified as the (1) people, (2) process, (3) equipment, (4) materials, (5) environment, and (6) management that may affect the problem. IPs working on an infection prevention problem would identify specific areas affecting the problem and document the specifics on the lines projecting from each criterion. The problem statement must be clear and concise in order to drill down into contributing factors.



**Figure 16-1.**

Example of an Ishikawa diagram

[View Image](#)



At the conclusion of the RCA, a team summarizes and identifies causes and begins to strategize about process redesign. Performing RCA analysis can complement other strategies that prove to reduce error and may generate ideas to improve practice. The RCA serves as a

formal structure to learn from past mistakes. Some organizations use the RCA only to determine causes of sentinel events and adverse drug events and not with incidents of near misses. When applied appropriately, the RCA targets change and identifies testable improvement hypotheses.

## FAILURE MODE EFFECT ANALYSIS

The FMEA tool is a proactive, preventive approach to identify potential failures and opportunities for error.<sup>9</sup>The manufacturing industry began using the FMEA approach when studying processes and equipment. The Veterans Affairs National Center for Patient Safety created the Healthcare Failure Mode Effect Analysis (HFMEA) to use in the healthcare industry. There are six main steps to conducting the HFMEA:

1. Determine a process or topic to study. Usually an organization selects a process that carries a high risk for harm if the process fails.
2. Convene a multidisciplinary team with process or content experts.
3. Develop a flow diagram that clearly identifies each step of the process and steps of any subprocesses.
4. Brainstorm possible reasons the process may fail and rate each step using a Likert scale with a severity number and probability of failure. For example, the team may determine that when administering medications, storing drugs with similar names close to each other could result in a patient receiving the wrong drug. The severity of the incident could result in severe harm to the patient, and the team rates the severity of the occurrence as high. The team may also determine a high likelihood of the event or a high probability.
5. After rating the failures and analyzing probabilities and occurrences, the team determines appropriate actions to take to eliminate the failure and redesign the process.
6. Finally, the team identifies outcome measures to test the redesigned process.

The Joint Commission's standards mandate that healthcare organizations conduct an FMEA or HFMEA every 18 months in an effort to improve patient safety. Many organizations find that conducting an FMEA or HFMEA reduces the risk of adverse patient events and proactively develop a systematic method for employees to perform process improvement.

## STRENGTHS, WEAKNESSES, OPPORTUNITIES, THREATS ANALYSIS

Organizations conduct a Strength, Weaknesses, Opportunities, Threats (SWOT) analysis to determine strengths, weaknesses, opportunities, and threats that face the organization.<sup>10</sup> Developed in a business context, the SWOT analysis helps companies carve out a sustainable niche in market share. Healthcare quality professionals and IPs use the SWOT analysis procedure to investigate public health issues and improve healthcare outcomes. For example, the IP might choose to perform a SWOT analysis with community health issues and may develop a tool similar to Table 16-2 that lists factors that affect disease prevention across a population.

**Table 16-2** Sample SWOT Analysis

<b>Strengths</b>  Public health efforts  Improved data with mandatory reporting of disease trends and outbreaks  Vaccination programs	<b>Weaknesses</b>  Infrastructure (personnel)  Workforce  Health information technology
<b>Opportunities</b>  Preparing for health threats  Eliminate health disparities  Disease surveillance  Improved laboratory testing and epidemiological findings	<b>Threats</b>  Rising healthcare costs  Continued health challenges such as tobacco use, poor diet, environmental and bioterrorism concerns

To conduct an effective SWOT analysis, the department or organization convenes a multidisciplinary team to answer questions, such as the following.

### *Strengths*

What advantages does the organization or program have?

What does the program do best?

What unique resources do the organization or program have available?

### *Weaknesses*

What could improve?

What should the organization or program avoid?

### *Opportunities*

What can the organization do to minimize loss and improve performance?

How will technology developments improve the program or organization?

What population or social profile changes will occur and provide additional program opportunities?

### *Threats*

What obstacles will the program or organization face?

What changes threaten the program?

Conducting this type of analysis points out what the organization should plan for, and how to use resources and guide efforts within a formal framework. Organizations may conduct a SWOT analysis

when developing a strategic vision, and IPs may use SWOT principles when developing or evaluating the infection prevention plan.

## Multivoting

Multivoting, also called nominal group technique, is the process of prioritizing a large list of topics to a final selection for performance improvement.<sup>11</sup> After brainstorming sessions that generate a list of ideas, performance improvement teams often use the multivoting process to make a decision about the top two or three areas to be addressed. Team members vote, ranking their selection in order of priority and after votes are tallied, select the project they will initiate. Teams can conduct multivoting several times to narrow the possibilities even further. IPs can use multivoting as a quick and easy method for determining goals and selecting interventions and when prioritizing efforts in the infection prevention plan.

## Goal-directed Checklists<sup>12</sup>

Checklists have been used in aviation for more than 60 years, and everyone in the cockpit is familiar with the checklists prior to takeoff. By applying checklists to the prevention of infection within an organization and using simple steps, such as washing hands and cleaning the skin with antiseptic, organizations can eliminate hazards and problems that affect patients every day. Aviation uses checklists to ensure pilots complete the most basic steps securing capacity for complex cognitive action.

The Institute of Healthcare Improvement (IHI) initiated a campaign to engage hospitals to improve patient care and reduce incidents of ventilator-associated pneumonia (VAP). One hospital, Genesys Regional Medical Center (GRMC), a 400-bed academic healthcare center, established a goal-directed checklist that contained multiple evidence-based criteria pertaining to VAP, line sepsis, and other aspects of intensive care unit (ICU) care. GRMC convened a multidisciplinary team consisting of physicians, leadership staff, nurses, respiratory staff, and pharmacists to start the quality improvement program. To achieve their project goal, the team developed a daily goals checklist. The tool contained criteria together called "bundles" for VAP and line sepsis. After educating the staff, the nurses and house staff caring for patients implemented the checklist each shift. Leadership staff reviewed the checklist to ensure that staff completed elements on the tool. GRMC found that using the goals checklist was effective in reducing the incidence of VAP and central line–associated bloodstream infections because the checklist provided an organized way to incorporate best practices.

## Process Control, Charts, Graphs, and Clinical Practice Guidelines

There are tools and methods to monitor and control variation within a process. Understanding variation requires knowledge of data. Statistical process control (SPC) assumes that the limits of randomization in any task or process can be measured and graphically illustrated to demonstrate the limits of the process. Processes that are within statistical control limits are considered to be under control. Processes that exceed control limits are considered out of statistical control, and adjustments in the process may be needed. SPC may also signal a special cause variation and need a focus study. An extensive overview of SPC is provided in Chapter 14 Statistical Process Control.

Variation is described as the difference in process steps and outputs. Consistent and predictable processes without variation are easier to improve than erratic processes. One of the first steps in the scientific approach requires elimination of variation in a process before manipulating the process to improve quality. This means that the process improver must stabilize the process and minimize random variation.



There are two types of variations: special cause and common cause variation. To understand special cause variation, individuals can think of special cause variation as not part of the system (or process) all of the time nor does it affect everyone; it arises out of specific circumstances. To reduce special cause variation, quality action teams and statisticians look for different conditions or procedures that lead to differences in results. Removing special cause variation results in a return to the average or expected performance level of the system achieved some time in the past. For example, an IP might seek to standardize a surgical practice across surgeons and eliminate variation in the antiseptic agents used to prepare the operative site. He or she might determine that a physician, who because of a complicated case used a different agent to prepare the surgical site, would demonstrate special cause variation.

Common cause variation, also called *random variation* or *second order change* or *noise*, is inherently part of the system (or process) over time and affects everyone and all outcomes. Variation is an output caused by the variation of inputs and to reduce common cause variation, the process or system must be fundamentally changed, designed, or redesigned. Reducing common cause variation improves the system beyond historical levels. The impact of change will be sustained far into the future. Reducing common cause variation usually results in improvement of several measures of the system simultaneously. For example, a high prevalence of group B streptococci in the community may result in a higher incidence of neonatal disease. If there is a higher prevalence in the community, group B streptococci cannot be eliminated or reduced unless screening process detects the higher prevalence.

Run charts are epidemiological tools used to identify how processes change over time. For example, if the organization examines the number of HAIs occurring within a hospital over a given period of time, clinicians will record each monthly value and graph the values, creating a chart that illustrates trends and averages. Run charts allow for the mean or average to be determined and show changes in the mean/average. Run charts also demonstrate special cause variation when there is a steady pattern of observation points falling above or below the mean/average line in an equal pattern.

Clinical practice guidelines are evidence-based standards, such as algorithms and consensus statements, that address reducing variation in practice and improving clinical outcomes. Healthcare organizations strategize about how to disseminate and implement guidelines that pertain to their service delivery. Developers of healthcare order sets, patient care plans, and care pathways routinely incorporate evidence-based clinical practice guidelines into their product in order to ensure optimal outcomes.

Affinity diagrams gather large amounts of language data and creatively group the data based on lines of natural relationships. Data are usually collected from brainstorming or customer surveys. Interrelationship diagrams take complex, multivariable problems and graphically display all of the interrelated factors. They may also suggest cause-and-effect relationships, thereby providing focus for the team or project. Fishbone diagrams map in detail the full range of paths and tasks that must be accomplished to achieve a primary or secondary goal.

Pareto charts are a series of vertical bars arranged and sorted in descending order of height from left to right with a cumulative percent line on the y-axis. Quality improvement and information technology specialists use Pareto charts to categorize data and compare units of data against the whole. Pareto charts allow a team to identify where their efforts will produce the greatest value, implying that 80 percent of benefit stems from 20 percent of causes.

## Six Sigma and the Lean Approach<sup>13</sup>

Six Sigma concentrates on precision and accuracy that leads to defect-free products or services. Toyota developed the methods to improve the speed, efficiency, and the elimination of waste. Six Sigma

originally arose in the manufacturing industry, specifically Motorola, to eliminate flawed products. The ability to identify waste, reduce it, and aggressively eliminate nonvalue added activities and improve responses to customers, whether internal or external, serves as the fundamental basis for the success of these two methods. Six Sigma and Lean methods have a proven track record since the beginning of the industrial revolution. Automotive industry leaders focused on improving performance and responding to customer expectations while reducing costs. Toyota fine-tuned Lean methods during the 1950s and 1960s, creating strategies such as value stream mapping, transactional mapping, and just-in-time training.

Value stream mapping is an excellent tool to visualize the current flow of materials and information in a core process. The map helps to identify bottlenecks, barriers, waste, or missing information. Value stream mapping helps to identify a range of improvement projects that a team can prioritize. Transitional mapping occurs when teams cannot clearly identify the details of a procedure. Individual experts often drive transitional processes and usually identify workarounds and how to effectively get the job done. Just-in-time training for employees shortens the time between learning a skill or process and application of the process or skill into daily work. When an employee needs to learn a new function or task, the employee logs into a system and starts learning. Automated learning can have financial benefits to the organization and streamline education for the employee.

Six Sigma and Lean principles use a DMAIC format. DMAIC is an acronym for five interconnected phases—define, measure, analyze, improve, and control—that create a data-driven quality strategy for improving processes. Each step in the cyclical DMAIC process ensures the best possible results. The following information further explains the process steps.

*Define* the customer, project boundaries, and improvement process.

- Define who customers are, what their requirements are for products and services, and their expectations.
- Define project boundaries, the beginning and end of the process.
- Define the process for improvement by mapping the process flow.

*Measure* the performance of the process involved.

- Develop a data collection plan for the process.
- Collect data from many sources to determine types of defects and metrics.
- Compare to customer survey results to determine shortfall.

*Analyze* the data collected and map the process to determine root causes and improvement opportunities.

- Identify gaps between current performance and goal performance.
- Prioritize opportunities to improve.
- Identify sources of variation.

*Improve* the target process by designing creative solutions to fix and prevent problems.

- Create innovative solutions using technology and discipline.
- Develop and deploy the implementation plan.
- Revisit the strategies of the plan.

*Control* the improvements to keep the process on the new course.

- Prevent reverting back to the "old way."
- Document the implementation of an ongoing monitoring control plan.
- Institutionalize or "hardwire" improvements in systems and structures.

A Six Sigma "black belt" designation means an individual has received extensive training in statistical analysis and Six Sigma methodology. Organizations that use Six Sigma and Lean tools assign a member of their senior leadership or a department executive to act as a project sponsor. For example, an IP may want to use Six Sigma principles in an effort to reduce surgical site infections.

## THE *PLAN, DO, STUDY, ACT* PERFORMANCE IMPROVEMENT MODEL<sup>14</sup>

When conducting any performance improvement or quality improvement function, team members must realize that the improvement and change is a cyclical activity. An organization or program team will not make just one change but will continually evaluate operations to determine further improvement. Beginning in 2009, TJC, the largest accrediting body in healthcare, through a standards improvement initiative, revised the *Infection Control and Prevention Standards* in a manner consistent with a quality model. TJC organized standards under the following categories: (1) planning that includes identifying risks and goals, (2) implementation, and (3) evaluation. The method TJC used to rewrite the *Infection Control and Prevention Standards* follows closely the Plan, Do, Study, Act (PDSA); or Plan, Do, Check, Act; or Test of Change cycle (Figure 16-2).

### *P*<sub>LAN</sub>

The planning phase of the standards includes identifying responsibilities for the program, available resources, risks and goals in the infection prevention plan, and identifying activities to achieve the goals and reduce risk of transmission of infection. Organizations must also have a plan to care for a large number of patients should community outbreaks occur.

### *D*<sub>O</sub>

The infection prevention and control program implements strategies specified in the plan to achieve the plan goals. Strategies may include but are not limited to conducting surveillance activities; performing staff and patient education sessions; ensuring adherence to evidence-based guidelines; developing various effective communication methods; describing external reporting methods; preparing emergency plans; conducting outbreak investigations; and developing appropriate organizational policies that address equipment sterilization, disposal, cleaning, disinfection, and staff transmission and exposure prevention practices.

### *S*<sub>TUDY</sub>

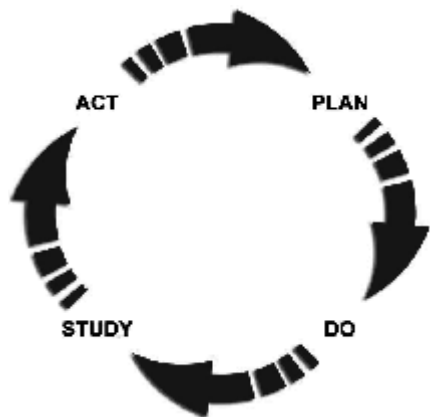
TJC makes clear in the *Infection Control and Prevention Standards* that organizations should align the plan with the goal of improving HAI rates. The organization must collect and display data to frontline staff about how well the organization actually achieves rate reduction. Data may include steps to increase staff influenza vaccination rates, reduce bloodstream infection and urinary catheter rates, and reduce rates of VAP. During the study phase of the cycle, data display, benchmarking, and trending become essential.

### *A*<sub>CT</sub>

**Figure 16-2.**



## Plan, Do, Study, Act Cycle.

[View Image](#)

An infection prevention and control program must continually change in order to achieve program goals and stay abreast of developments that affect patient safety and infection prevention. Clinicians and quality improvement professionals repeat the PDSA cycle as often as necessary until they determine adequate and appropriate changes to processes.

Process owners must make available to committee and team members data that contain achievable benchmarks and thresholds. Data analysis requires clear display of achieved outcomes. Many institutions rely on the information technology assistance to abstract

data, record, and even graph data that trend improvement over time. Qualitative data may be obtained from in-depth, open-ended interviews, direct observation, and written documents, such as questionnaires, diaries, and records. Quantitative data can be obtained from a surveillance program, facility case mix databases, and medical records.

The process improvement change cycle requires the change leader to have knowledge of quality improvement tools and effectively arrive at an outcome. Proposed improvement activities should complement each other. System design starts with a focus on outcomes and asks: "How do we design systems that achieve the desired outcome?" Planners must decide whether processes are needed and what value they add to the program's mission. Process improvement also requires knowledge of the program's scope, the system of delivery, and types of services. An understanding of the scope of service and how the system works provides the foundation for discussion, ideas, process change, and improved outcomes.

## Customer Satisfaction

A quality-based infection prevention and control program focuses on internal and external customers and includes a process that regularly assesses and evaluates how the program meets the needs of the organization and community customers. Within the organization, healthcare personnel must understand their prevention role and integrate their responsibilities to reduce exposure to infection into daily activities. As internal customers, staff receives and analyzes surveillance data, reviews program policies, and receives ongoing education about infection prevention. External customers consist of individuals or groups outside of the immediate organization, such as patients, family members, the community at large, physicians, public health departments, agencies such as the Centers for Medicare & Medicaid Services (CMS), TJC, the Occupational Safety and Health Administration (OSHA), and the Centers for Disease Control and Prevention (CDC). External customers expect evidence-based practice and compliance with rules, regulations, and guidelines to prevent and control disease. External customers also expect that organizations monitor their performance and alert them with any findings suggesting a health hazard or infectious outbreak. Infection prevention and control programs measure customer expectations in many different ways, such as conducting satisfaction surveys, establishing complaint hot lines, encouraging dialogue, and through interviews taking suggestions on how to improve the program.

## Conclusions

In summary, infection prevention and control programs incorporate broad responsibilities and must use a variety of approaches and methods to ensure quality, safe healthcare. A simple model of planning, implementing, monitoring, and sustaining improvement must ensure compliance with current regulations and accreditation standards. Performance improvement is an ongoing continuous cycle that focuses on patient clinical outcomes and customer satisfaction and service. Measuring performance determines program effectiveness and efficiency and determines whether proactive approaches or retrospective analysis of high-risk processes can further improve the infection prevention and control program.

## Future Trends

IPs must rely on information technology to assist them with collecting valuable clinical data and information. They must analyze surveillance data to determine variances and act appropriately to define populations at risk of infection. Today, many state laws mandate public reporting of infection prevalence rates and comparison of local and national outcome data. As an industry, infection prevention has become transparent, with attention to global epidemiological surveillance of communicable disease. In every discussion about HAI prevention, a movement requires a change from current state to future state. IPs must learn change techniques and implement quality improvement practices that identify innovation and support or apply research into practice.

## Supplemental Resources

McCannon CJ, Schall MW, Perla RJ. *Planning for Scale: A Guide for Designing Large-Scale Improvement Initiatives*. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement, 2008. Available at:

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## Performance Measures

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### Abstract

*During the past several years a great deal of work has been accomplished nationwide on the development and use of performance measures. The Joint Commission launched its ORYX outcome measures in 1998.<sup>1</sup>The Centers for Medicare & Medicaid Services launched national comparative measures for long-term care in 2002, home care in 2003, and hospital reporting with the National Voluntary Hospital Reporting Initiative in 2004.<sup>2</sup>The Institute of Medicine published its reports on quality: To Err Is Human<sup>3</sup>in 1999 and Crossing the Quality Chasm<sup>4</sup>in 2001. The Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee includes performance measures in its evidence-based guidelines,<sup>5</sup>and the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America have included indicators in the Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals.<sup>6</sup>The Department of Health and Human Services has developed national performance indicators to guide a nationwide agenda for measuring healthcare-associated infections.<sup>7</sup>The quality world has come to be much more definitive and sophisticated with regard to the use of indicators. This chapter reviews many of the systems and processes available for measuring quality and provides a framework for evaluation, development, and use of effective indicators.*

## Key Concepts

- Performance measures focus on outcomes or processes and are used for internal improvement purposes, intra- or interorganizational comparisons, and by various external entities for making decisions about care.
- Setting clear priorities for measurement and improvement precedes selection of performance measures.
- Selecting existing performance indicators requires careful evaluation to ensure they meet rigorous criteria and the organization's needs.
- Developing new performance measures necessitates adherence to detailed criteria to ensure reliable and valid measurement activities.

## Introduction

Measuring and reporting the quality of care is a well-established concept. The ideas of two often-cited healthcare professionals preceded the current obsession with measurement of healthcare quality. In the 19th century during the Crimean War, Florence Nightingale collected mortality data and related it to the lack of sanitary conditions. She was instrumental in the development of vital statistics and methods for collecting and displaying health-related data, including creating a new data display that posted the statistic of interest as a proportion of a wedge within a circle (Figure 17-1).<sup>8</sup>In the early 20th century,

Dr. Ernest A. Codman proposed to his colleagues in Boston that they measure their own surgical outcomes and disclose them to the public, thus allowing future patients to make their choice of a surgeon based on "end-results."<sup>9</sup>Ms. Nightingale's work continued with the measurement of vital health statistics and use of statistics in healthcare. Dr. Codman's ideas eventually led to the establishment of The Joint Commission (TJC). However, it took almost a full century for his end-results theory to catch on.

Today's healthcare environment is significantly challenged with balancing financial and quality concerns. Increased public awareness of access, quality, and cost issues has led to a multitude of demands for performance data and expectations of improved, positive results. The government has initiated strict rules for value-based payment for organizations based on their quality and safety results generated during delivery of care. Nonpayment for healthcare-associated infections (HAIs) is also enforced by the Centers for Medicare & Medicaid Services (CMS) as well as many private payers.<sup>10</sup>In response to these increased data demands, healthcare professionals have standardized performance measures, complied with data submission requests (including those that are voluntary), and contributed to the design of report formats for public review. Most importantly, they have also increased their efforts to prevent HAIs.

**Figure 17-1.** Example of a polar-area diagram, invented by Florence Nightingale

[View Image](#)



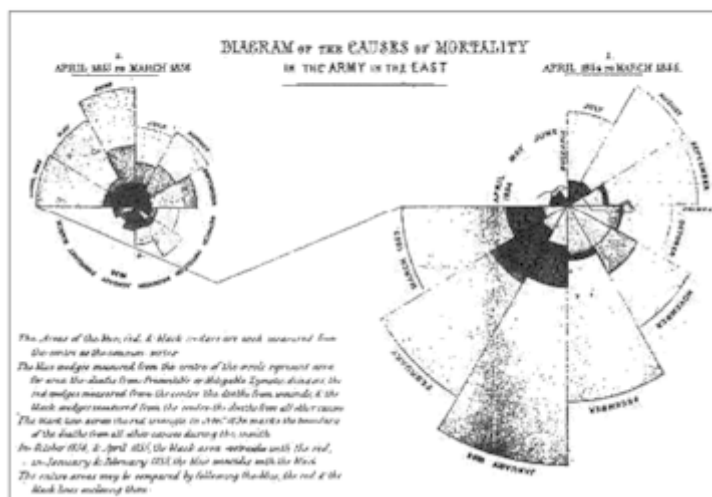
**Figure 17-1.** Example of a polar-area diagram, invented by Florence Nightingale. The original was in color, with the outer area in blue, the central darker areas in black, and the central lighter areas in red. The text in the lower left corner reads:

The Areas of the blue, red, and black wedges are each measured from the centre as the common vertex.

The blue wedges measured from the centre of the circle represent area for area the deaths from Preventable or Mitigable Zymotic diseases, the red wedges measured from the centre the deaths from wounds, & the black wedges measured from the centre the deaths from all other causes.



# Polar-Area Diagram



The black line across the red triangle in November 1854 marks the boundary of the deaths from all other causes during the month. In October 1854 and April 1855, the black area coincides with the red, in January and February 1855, the blue coincides with the black. The entire areas may be compared by following the blue, the red, and the black lines enclosing them.

This chapter reviews the history and contemporary background of measuring infection prevention practices and measures that are currently in use nationally, provides guidance on how to develop new and evaluate existing performance measures, and discusses how to use performance measurement data.

The effective use of reliable and valid measures is fundamental in the quest to reduce infection risk, improve patient safety, and prevent wasted effort and expenditure of healthcare dollars.

## Background

During the past 40 years, tremendous accomplishments have been made toward measuring and improving infection prevention activities. These accomplishments are briefly reviewed chronologically to provide the background relevant for understanding the current requirements and recommendations for measuring and reducing HAIs.

### The Early Years: 1970–2004

The Centers for Disease Control and Prevention (CDC) established the National Nosocomial Infection Surveillance System (NNIS) in 1970 to encourage hospitals in the United States to report their nosocomial (healthcare-associated) infection surveillance data for aggregation into a national database.<sup>11</sup>

NNIS has been replaced by the National Healthcare Safety Network (NHSN).<sup>12</sup> Because HAIs are considered to be valid outcome measures by most healthcare practitioners, the infection preventionist (IP) should be familiar with the most recent NHSN publications. NHSN performance measures are discussed in the next section.

The Study of the Efficacy of Nosocomial Infection Control (SENIC), performed in the mid-1970s and early 1980s, identified structures and processes associated with lower infection rates.<sup>13</sup> The goals of the study were to measure the use of infection prevention and control programs, identify specific surveillance and infection prevention characteristics, and determine whether infection prevention and control programs were effective in reducing nosocomial infection rates. The study concluded that as many as 32 percent of infections could be avoided if four components were present in an infection prevention and control program: (1) a system of ongoing surveillance of infections; (2) active efforts to control infections; (3) qualified infection prevention staff; and (4) for surgical wound infections, feedback of infection rates provided to surgeons. The study also concluded that exact measures that are most effective differ for different infection sites.



In 1985, TJC undertook an initiative to change its approach to accreditation to one that included the review of performance measurement data—"results."<sup>1</sup> Dubbed "the Agenda for Change," several expert panels were convened to define outcome and process measures that would be used in the survey process of the future. One such panel focused on results of hospitals' infection prevention and control programs. Chaired by Robert Haley, MD, the project director of the SENIC study, and including experts from surgery, medicine, epidemiology, nursing, dentistry, and quality improvement, the panel identified eight measures for national testing and eventual implementation.<sup>14,15</sup>

Also in 1985, the Maryland Hospital Association initiated the Quality Indicator Project (MHAQIP) to assist hospitals in measuring and improving the quality of care.<sup>16</sup> It began as a small voluntary project involving seven hospitals designed to provide tools to hospital trustees, management, and medical staff leadership to improve hospital performance. Of key interest, then and now, were HAI rates. The Quality Indicator (QI) Study Group was created in 1993 by the governing boards of the *Society for Healthcare Epidemiology of America* (SHEA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Surgical Infection Society (SIS).<sup>17</sup> The QI Study Group conducted a literature review, interviewed experts in the field, and focused on how best to evaluate quality indicators (performance measures), with an emphasis on HAIs. The study evaluated quality indicators used in epidemiology, HAI control, infection prevention, and quality-of-care improvement. This report reviewed pertinent issues and, when possible, provided specific advice on how to evaluate quality indicators and quality indicator systems to enable the reader to be able to discuss, develop, and evaluate quality indicators, and better collect, aggregate, analyze, and use quality data.<sup>17</sup>

TJC's ORYX reporting system began in 1998.<sup>1</sup> All accredited hospitals were required to select a data intermediary (vendor) and begin submitting at least four measures on a quarterly basis. The data were intended to provide comparisons of multiple facilities and evidence of a hospital's internal performance improvement activities and were to be used in the accreditation process of hospitals. Beginning in January 2003, TJC instituted the next level of measures, referred to as "core measures." Core measures are designed around diagnostic groups, such as acute myocardial infarct, community-acquired pneumonia, and heart failure.<sup>18</sup> Of interest to IPs were the pneumonia process measures: patients who receive their first dose of antibiotics within 4 hours after arrival at the hospital, patients older than 65 years who are screened for pneumococcal vaccine status, and patients who are administered a vaccine prior to discharge. In 2011, TJC identified some of the core measures as "Accountability Measures" as ones that meet four criteria:

- **Research:** Strong scientific evidence exists demonstrating that compliance with a given process of care improves healthcare outcomes (either directly or by reducing the risk of adverse outcomes).
- **Proximity:** The process being measured is closely connected to the outcome it impacts; there are relatively few clinical processes that occur after the one that is measured and before the improved outcome occurs.
- **Accuracy:** The measure accurately assesses whether the evidence-based process has actually been provided. That is, the measure should be capable of judging whether the process has been delivered with sufficient effectiveness to make improved outcomes likely. If it is not, then the measure is a poor measure of quality, likely to be subject to workarounds that induce unproductive work instead of work that directly improves quality of care.
- **Adverse effects:** The measure construct is designed to minimize or eliminate unintended adverse effects.

Based on these criteria, the accountability measures will produce the greatest positive effect on patient outcomes when hospitals demonstrate improvement of them.<sup>19</sup>

In October 2003, the CMS began to report data on its website: [medicare.gov/hospitalcompare](http://medicare.gov/hospitalcompare) for a set of 10 hospital quality measures submitted voluntarily by hospitals. Under a federal law, CMS required hospitals to submit quality performance data on these required quality measures to receive the full annual payment update.<sup>2</sup> Initially, hospitals that did not participate in the "Reporting Hospital Quality Data for Annual Update" program were penalized a 0.4 percentage point reduction in the annual market basket (the measure of inflation in costs of goods and services used by hospitals in treating Medicare patients). The Deficit Reduction Act of 2005 increased that reduction to 2.0 percentage points. Most hospitals are now submitting the requested set of measures. Current penalties have evolved to now focus on actual rates of occurrence.

In 2004, TJC added core measure rates to its Quality Check website ([www.qualitycheck.org/consumer/searchQCR.aspx](http://www.qualitycheck.org/consumer/searchQCR.aspx)), which displays hospitals' quarterly rates. In addition, the number of required sets for submission by hospitals increased from two to three. Also in 2004, the Institute for Healthcare Improvement (IHI) launched a major effort, the 100,000 Lives Campaign, to increase the pace of improvement in patient safety in hospitals. Organizations agreed to use consistent evidence-based interventions and performance measures to monitor and reduce the risk of infections and other outcomes. Among the measures were preventing central line-associated, surgical site, and ventilator-associated infections.<sup>20</sup> The campaign was successful, and in 2006 the IHI expanded the focus with its 5 Million Lives Campaign, adding another important measure of methicillin-resistant *Staphylococcus aureus* infections.<sup>20</sup> The IHI also sponsors breakthrough improvement projects for HAIs and other patient safety and quality efforts through their IMPACT program, which includes measures and benchmarks for performance.<sup>20</sup>

Two other groups that have promoted the use of infection prevention measures and strategies are the National Quality Forum (NQF)<sup>21</sup> and The Leapfrog Group.<sup>22</sup> Included on NQF's list of safe practices are strategies associated with hand hygiene and the prevention of central line infections, ventilator-associated pneumonias, and surgical site infections (SSIs). The Leapfrog Group has included the NQF's safe practices in its annual survey of hospitals.

Also of major relevance to infection prevention are the Surgical Care Improvement Project (SCIP) Core Measures, first described by TJC, and then synchronized with CMS definitions.<sup>23</sup> The set includes six measures intended to reduce SSIs. Three of the measures relate to the timing, selection, and duration of prophylactic antibiotic use and are stratified by several types of surgical procedures. The remaining three relate to blood glucose control with cardiac surgery patients, appropriate hair removal, and immediate postoperative normothermia with colorectal surgery patients.

### Current Status of Performance Measures: 2005 to Present

Three important changes have occurred since 2005 that continue to drive expectations related to the measurement and improvement of infection prevention strategies. In 2006, TJC announced a new infection prevention standard that requires accredited hospitals, critical access hospitals, and long-term care organizations to offer influenza vaccinations to staff effective January 1, 2007. Part of this standard is the requirement to measure rates of influenza immunizations and to use these data to increase staff's acceptance of the vaccine. The 2013 Joint Commission Standards strengthened this requirement by requiring each organization to have a proactive vaccination program, education, and a goal for

immunization.<sup>24</sup>The NHSN has also added a measure for surveillance for healthcare personnel influenza immunizations.<sup>25</sup>

TJC has also introduced National Patient Safety Goals (NPSGs) for prevention of HAIs. For hand hygiene, the NPSGs require that organizations demonstrate compliance with the CDC or World Health Organization (WHO) guidelines for handwashing and hand hygiene. Hand hygiene compliance should be measured to assess compliance and guide future improvement efforts.<sup>26</sup>In 2010, three additional NPSGs required monitors of both processes and outcomes related to prevention of multidrug-resistant organisms (MDROs), central line-associated bloodstream infections (CLABSI), and SSIs.<sup>26</sup>Recently a sixth NPSG was added that focused on catheter-associated urinary tract infections (CAUTIs), again with requirements for monitoring these infections.<sup>26</sup>

The NHSN replaced the former NNIS at the CDC in 2005 when it first accepted applicants into the program. The NHSN has created patient safety modules that include surveillance criteria for identifying HAIs related to devices and procedures, as well as MDROs, *Clostridium difficile* infections (CDI), and vaccinations. These criteria are reviewed and updated periodically, as are the methods of data collection and analysis.<sup>27</sup>In 2011, the CDC convened a working group to revise the criteria for surveillance of ventilator-associated events using a tiered approach that looks at ventilator-associated conditions (VAC), ventilator complications related to infections (IVAC), and ventilator-associated pneumonia (VAP).<sup>28</sup>

Currently the NHSN monitors events related to CLABSI and central line insertion practices (CLIP), ventilator-associated events (VAE), VAP, CAUTI, dialysis incidents, antimicrobial use and resistance, and SSIs. Monitors focus primarily on intensive care units (ICU) and high-risk outpatient areas (e.g., dialysis). Adult, pediatric, and neonatal patients can be monitored. The NHSN criteria are important performance indicators. They form a robust national database against which organizations can compare and benchmark their own HAI performance results to examine the magnitude and staff adherence to practices associated with these infections.<sup>29</sup>

In 2008, the CMS instituted a nonpayment position for the treatment of 10 hospital-associated conditions, among them several related to infections: CAUTI; vascular catheter-associated infection; mediastinitis SSI following coronary artery bypass graft (CABG) surgery; bariatric surgery; laparoscopic gastric bypass; gastroenterostomy; laparoscopic gastric restrictive surgery; and orthopedic procedures of the spine, neck, shoulder, and elbow.<sup>30</sup>These requirements underscore the need for organizations to measure and reduce the occurrence of HAIs or potentially receive a lesser reimbursement for patient care.

In a collaborative effort, SHEA and the *Infectious Disease Society of America (IDSA)* joined with other organizations, including APIC, to develop *A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*.<sup>6</sup>Released in late 2008, the *Compendium* is a concise set of practical recommendations for the prevention of common HAIs, including CLABSI, SSI, CAUTI, VAP, methicillin-resistant *Staphylococcus aureus*, and CDIs. With a focus on implementation, the *Compendium* synthesizes previously published guidelines with a set of basic HAI prevention strategies, recommends that accountability for implementing infection prevention practices be assigned to specific groups and individuals, and includes proposed performance measures for internal quality improvement efforts. The *Compendium* is currently under review and publication of section updates are planned for 2014.

There are now hundreds of experts and more than 20 years of experience in healthcare that have been devoted to developing and testing performance measures. Significant progress has been made in determining the criteria for selecting, evaluating, and developing performance indicators that guide the development of measures.<sup>5,31,32,33,34</sup> The following sections discuss the considerations for selecting and developing performance measures for infection prevention.

## Selecting Performance Measures

Setting clear priorities for measurement and improvement precedes the selection of performance measures. The leaders of the organization should review external requirements and also establish internal measurement requirements with input from the professionals in the field. Priorities from external entities will include federal and state regulations, accreditation, payer/purchaser expectations, and areas known to be of interest to the community of patients served. For internal requirements, priorities include services in need of improvement, medical staff's concerns, and clinical care that represents high-risk or high-volume services that warrant monitoring. Once priorities are defined by the organization's leaders, the selection of measures can begin.

The selection of performance measures for specific HAIs should focus on measures that have clear-cut definitions, provide precise and usable information, are supported by prior studies, and can be applied readily in most hospitals, long-term care facilities, and ambulatory care settings. They should also be considered clinically important for a given patient population and helpful to healthcare leaders.

"No indicator can be perfectly appropriate for every institution or for every patient population. It is important to avoid overly broad indicators, such as 'all' HAIs,"<sup>17</sup> because these indicators do not provide enough specificity to guide improvement activities. Some important indicators, such as CAUTIs, have been more easily defined, detected, and measured while others such as VAP have been more difficult to measure accurately and have recently been revised by the NHSN to be more specific.<sup>28</sup> Criteria for HAIs have evolved over time. Early criteria from the CDC<sup>35</sup> provided initial guidance to practitioners and are more precise in their current updated form as described in the Patient Safety Module from the CDC.<sup>27</sup> Another example for increased precision is a methodology that offers multiple options for measuring MDROs in an organization that will provide more accurate and specific information about the incidence of colonization, infection, and healthcare-associated and community-acquired pathogens.<sup>36</sup>

## Fundamental Concepts

As noted, the development of valid performance measures has come a long way in healthcare. It has moved beyond the infancy stage to a time of clear definitions and explicitly defined criteria for evaluating the soundness of a measure. This section reviews fundamental concepts, measures evaluation criteria, and provides guidance for developing new measures when necessary.

### *TYPES OF MEASURES*

A measure is a valid and reliable indicator that can be used to monitor and evaluate the quality of important governance, management, clinical, and support functions that affect patient outcomes.<sup>37</sup>

*Valid* means "the extent to which a measure accurately reflects the concept or construct that it is intended to measure."<sup>37</sup> *Reliable* means "the ability of the indicator to accurately and consistently identify

the events it was designed to identify across multiple health care settings."<sup>37</sup>A *performance measure* is a quantitative tool that provides an indication of an organization's performance in relation to a specified process or outcome.<sup>37</sup>A *clinical measure* is a type of performance measure designed to evaluate the processes or outcomes of care associated with the delivery of clinical services; allow for intra- and interorganizational comparisons to be used to continuously improve patient health outcomes; and focus on the appropriateness of clinical decision-making and implementation of these decisions. Clinical indicators must be condition specific, procedure specific, or address important functions of patient care (e.g., medication use, infection prevention, patient assessment).<sup>37</sup>

### OUTCOME MEASURES

An outcome measure is a measure that indicates the result of the performance (or nonperformance) of a function(s) or process(es). Clinical outcome measures can describe desirable or undesirable events. Outcome measures used in infection prevention usually describe undesirable events, such as SSI, CLABSI, or CAUTI rates. Cost is an outcome indicator that reflects efficiency and is helpful in understanding the balance between cost and benefit, such as the cost of needleless syringes versus the potential cost of healthcare-associated hepatitis in healthcare personnel. Patient experience outcomes (often referred to as "satisfaction") describe the patient's perception of the care received. For example, studies show that patients who require isolation for an infection express decreased satisfaction with their hospital care.<sup>38</sup>The use of HAIs as clinical performance outcome measures is generally well accepted because of the long history of use and practitioners' comfort with definitions and data collection methodologies.

### PROCESS MEASURES

A process measure focuses on a process or the steps in a process that leads to a specific outcome. It is believed that a scientific basis exists to assume that the process, when executed well, will increase the probability of achieving a desired outcome. Process measures can be useful to evaluate quality if they can be linked to an outcome measure (e.g., use of maximal sterile barriers when inserting a central venous catheter and subsequent CLABSI).<sup>39</sup>

Process measures are commonly used to evaluate compliance with desired care or support practices or to monitor variation in these practices. They may also be used when the outcome to be measured is rare in occurrence or difficult to measure (e.g., infections after endoscopy) or when there is difficulty acquiring the data (e.g., contacting the discharged and relocated patient after surgery). Process measures are also helpful in evaluating the effectiveness of an educational effort as a measure of behavior (e.g., compliance with aseptic technique for dressing change) or performance of basic infection prevention procedures, such as hand hygiene.

Many process measures are incorporated in the CDC's HICPAC Infection Prevention Guidelines. The category 1 and 2 recommendations lend themselves well to this type of monitoring. For instance, the category 1A recommendation to administer a preoperative antibiotic within 1 hour prior to incision in appropriate patients is commonly monitored in assessing processes that can reduce SSI risk.<sup>40</sup>The CMS also uses this performance indicator in their SCIP measures.<sup>41</sup>The *Compendium* has also highlighted both outcome and process indicators for each of the six areas discussed.<sup>6</sup>

## Determining the Patient Population to Measure

Two important issues should be considered when determining the patient population to measure. The first relates to whether the patient characteristics contribute to the likelihood that the outcome will occur, suggesting that risk adjustment or stratification may be necessary. Risk adjustment is a methodology that is often thought of as a way to "level the playing field" across hospitals when making comparisons by considering the hospital's patient population and patients' differing tendencies to develop the outcome in spite of the caregivers' best efforts to prevent them. The methodology makes comparisons of rates across hospitals that are more fair and valid. In addition, a hospital can compare its risk adjusted (predicted) rate to its actual rate for an outcome to determine if there may still be opportunities for improvement. If the hospital's actual rate is higher than its predicted rate, operational and clinical structures and processes aimed at preventing the event may not yet be at an ideal level of performance. The second issue is associated with the volume of patients in the population of interest. A large volume of patients suggests sampling may be appropriate, whereas a small volume may raise questions about the interpretability of results or require that the entire population be analyzed.

### *RISK POTENTIAL*

When individual patient characteristics increase the likelihood of the outcome of interest, it is necessary to adjust the metrics to control for these risks. If the patients in the main population of interest are likely to present different levels of risk for experiencing the event of interest (e.g., CLABSI), there are two options for selecting the population to measure: (1) narrow the population of interest and only collect data on a homogenous group of patients; or (2) collect additional data on a broad population of patients to enable risk-adjustment or stratification of rates.

If it is not possible or desirable to narrow the focus of the population to a homogenous group, then it may be necessary to collect additional data for each patient to allow for mathematical adjustment that controls for the differences among patients in a heterogeneous group. Because rates may be tracked over time and compared across units, services, and institutions, it may be important to stratify the data by separating it into homogeneous subgroups. Usually, the more specific the stratification is, the more meaningful the comparison.

For example, SSI rates can be divided into groups, or strata, that account for differences in infection risk. Early studies indicated advantages to stratifying SSI data. In a large prospective study in the early 1980s, Cruse examined nearly 50,000 surgical wounds over 10 years using the National Research Council wound infection definitions of risk stratification and with a focus on clean surgeries as a prime indicator for surgical technique and outcomes.<sup>42,43</sup> Data in a study by Haley et al. demonstrated that

SSIs could be better predicted using a simple multivariate analysis than looking at wound contamination alone.<sup>44</sup> Historically, the NHSN has used a simple risk stratification process for SSIs that included the general physical status of the patient (the American Society of Anesthesiologists [ASA] preoperative classification score),<sup>45,46</sup> wound contamination classification, and the duration of the procedure. Following analysis of this risk stratification strategy, the NHSN has developed a new risk model for this analysis. This model uses existing data elements collected through the NHSN that improve the predictive performance of the elements as compared to the traditional NHSN risk index stratification methodology.

47

### *SAMPLE SIZE*

When the volume of patients in the selected population is large, a sampling approach to data collection may be an acceptable way to minimize resources used for collection and still obtain valid data. Selecting a sample of eligible patients requires knowledge of sampling theory and methods to ensure randomness



and generalizability of results. Common sampling methods used in infection prevention and epidemiologic analysis include general random samples, or stratified random samples, such as every third surgery or every tenth admission.

The limitations of small sample sizes should be considered when selecting either process or outcome measures. Although the data collected may be accurate, the analyses and subsequent conclusions may be limited by small numbers in the studied population, requiring measurement of the entire population at risk. Organizations with small populations may be restricted in their ability to get large enough numbers to have confidence in their data. Few guidelines exist regarding how to address the evaluation of performance measures in such settings. Some studies propose using process measures that have documented association with specific high-quality outcomes. Because the outcome is so uncommon, monitoring of process measures that have been documented to prevent the untoward events would be more appropriate.

## Data Analysis

Another fundamental concept of performance measurement centers around two main issues of data analysis: the method of calculation, and the use of risk-adjustment and stratification techniques.

### *METHOD OF CALCULATION*

A performance measure is comprised of a *numerator* and *denominator*. The numerator is the event being measured. It describes the outcome or process of interest, such as the number of patients who fall, the number of patients with a CAUTI, or the number of times maximal sterile barriers are used when inserting a central line. The denominator is the population at risk. Those are the patients, residents, healthcare personnel, or others who are subject to experiencing the event defined in the numerator.

There are three ways that performance measures are calculated: by (1) rate, (2) continuous variable, or (3) ratio. For all three types of measures, there must be clear definitions of the population of interest and the event of interest.

A rate-based measure is derived by dividing the numerator by the denominator (population at risk) within a designated time frame, and multiplying by a selected multiplier. If the multiplier is 100, this will result in a percentage of patients in the population of interest who experienced the event described by the numerator, such as the percentage of patients who develop mediastinitis after CABG surgery or the percentage of time patients are placed into Contact Precautions when they are colonized or infected with *Clostridium difficile*. When rates are calculated, the numerator is a subset of the denominator. This rate can be calculated as an incidence rate (i.e., the number of new cases during a time period, such as the rate of patients with urinary catheters who get a CAUTI during the first quarter of the year). When describing the incidence of infections during an outbreak investigation, the incidence rate is sometimes called an attack rate. When the calculation includes existing cases during a time period, this is called a prevalence rate. For example, one can measure the prevalence of all patients with CAUTI, both new and existing cases, on one day in a long-term care facility. These are frequently used outcome performance measures when there are limited surveillance resources and may be repeated over time for greater confidence in the rates.

A continuous variable measure is calculated when many results are possible (e.g., days of hospital stay, minutes to treatment). For example, the performance measure that evaluates the length of time between diagnosis of pneumonia and the first dose of antibiotics requires that this time interval be collected for



every patient diagnosed with pneumonia (the population at risk), usually in hours. An average, or mean time, is then calculated using all pneumonia patients' time intervals.

A ratio-based measure depends on the relationship between two counted sets of data and may have a value of zero or greater. In a ratio, the numerator is not necessarily a subset of the denominator. For example, a frequently used ratio-based measure used in infection prevention is the relationship between the number of patients with central lines who develop a bloodstream infection to the number of central line days for the same time period. This is called an incidence density.<sup>48</sup> Another measure is the standardized infection ratio (SIR). This is calculated by dividing the observed number of SSIs by the expected number predicted. This calculation generates a single number that is used by some infection prevention and control programs to monitor and provide feedback of risk-adjusted SSI rates to surgeons. The SIR can provide a quality index, regardless of the mix of operations performed, and is well suited to control chart techniques and for providing valid inter-hospital comparisons.<sup>49</sup>

### *RISK ADJUSTMENT AND STRATIFICATION*

When assessing a healthcare process or outcome indicator, either within or across organizations, it is important to adjust for case-mix and severity.<sup>50</sup> Risk adjustment is a statistical process for reducing, removing, or clarifying the influences of confounding factors that differ among comparison groups; it is mostly used with outcome measures to adjust for confounding patient factors in order to have more fair comparisons.<sup>37</sup> Two methods for controlling the impact of patient characteristics (factors) are: (1) simple stratification used when there is a patient factor of concern, and (2) a more complicated mathematical method that controls for several patient factors believed to influence the occurrence of the event.<sup>47</sup>

Stratification is a form of risk adjustment that involves classifying data into subgroups based on one or more characteristics. For example, a measure's population might be stratified by gender before calculating rates, resulting in separate rates for males and females. In infection prevention, it is common to stratify infants by birth weight when assessing infections and infection risk or to stratify sharps injuries by time of day, role, and unit. Each subgroup becomes a separate denominator (population of interest) with the numerator event of interest the same for the subgroups; separate rates are then calculated for each subgroup.

When several factors are believed to contribute to the outcome, simple stratification cannot control for all factors at one time and thus, is not sufficient; statistical modeling and risk-adjustment methods such as multivariate analysis should be used. Patient level data for factors believed to contribute to the occurrence of the outcome are included in a risk-adjustment model (statistical algorithm) and used to generate a risk-adjusted rate for the measure. This statistical method is used when it is difficult to separate patients into homogeneous groups based on single contributing factors. If separating patient populations according to single factors is possible, then stratification is an easier process for addressing comparability of rates.

## **Evaluating Existing Performance Measures**

Experts agree that the key consideration when evaluating measures is to be clear about the purpose of measurement. The evaluation criteria for a measure that will be used within a single organization are included in Table 17-1. As the purpose of measurement extends beyond the single organization, these same characteristics are necessary, as well as assurance there is comparability across organizations. Finally, when measures are used to make decisions related to accreditation, purchasing, and selection for care, healthcare organizations expect even greater precision and validity than when the measure is

used only for performance improvement purposes. The NQF has developed explicit criteria for a measure that is to be used for public reporting of an event (see Table 17-1).

When evaluating performance measures to meet internal priorities, it is important to first determine how the data will be used: internal improvement purposes only, comparison with other organizations, or to provide information for consumers' selection of care. To meet external requirements, such as accreditation, regulation, or purchasing (in which case the measures are probably prescribed), it is prudent to determine if measures that will meet the organization's purpose already exist because developing reliable and valid measures is time consuming and challenging.

TJC's attributes for *Core Performance Measures and Associated Evaluation Criteria*<sup>32</sup> can be used as a framework for evaluating existing measures. Table 17-2 lists the main attributes and provides infection prevention-specific examples and references added by the authors.

**Table 17-1.**Measure Evaluation Criteria<sup>33</sup>

**Table 17-1** Measure Evaluation Criteria

1. Importance to measure and report
2. Scientific acceptability of measure properties
3. Feasibility
4. Usability and use
5. Related and competing measures

It is of primary importance when evaluating an existing measure to determine whether the measure adequately defines the event and patient population of interest to the organization. Clear definitions for each data element are necessary to ensure collection of the correct data values required for identifying and calculating the population and event (performance measure). For example, using all patients on a general medical unit as the denominator when measuring the incidence of CAUTI is misleading because many patients will not have urinary catheters and therefore are not at risk for this type of infection. Specific instructions for collecting the data (source, time frame, and sampling) will also support reproducibility of measurement results and fair comparison. Each measure should be reliable and valid, and adequately risk adjusted when patient factors are known to influence the metric. The measured event should be within the organization's control, and results must be interpretable by the organization in order to make changes and improvements when indicated. Accurately using criteria for HAIs can be challenging. Recently the *American Journal of Infection Control*(AJIC) collaborated with the NHSN to publish case studies to assist infection preventionists in analyzing quality data leading to the correct identification of HAI.<sup>51,52,53</sup>

**Table 17-2.**Attributes and Characteristics of Performance Measures for Infection Prevention<sup>32</sup>

**Table 17-2** Attributes and Characteristics of Performance Measures for Infection Prevention

Attribute of the Measure	Characteristics	Application to Infection Prevention
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Targets improvement in a health population	Designed to address performance improvement likely to have a significant impact to the health of a specified population	<p>Example: Reducing catheter-associated urinary tract infections in patients in medical intensive care units and other clinical units</p> <p>Meddings J, Rogers MA, Krein SL, et al. Reducing unnecessary urinary catheter use and other strategies to prevent catheter-associated urinary tract infection: an integrative review. <i>BMJ Qual Saf</i> 2013 Sep 27 [Epub ahead of print].</p>
Precisely defined and specified	Measure is standardized; has explicit predefined requirements for data collection and calculation of the measure	<p>Example: National Healthcare Safety Network (NHSN) criteria for catheter-related bloodstream infections: criteria and calculations</p> <p>Centers for Disease Control and Prevention (CDC). Patient safety component training. CDC website. 2013. Available at: <a href="http://www.cdc.gov/nhsn/Training/patient-safety-component/">http://www.cdc.gov/nhsn/Training/patient-safety-component/</a>.</p>
Measure is reliable	Measure will consistently measure the events it was designed to measure within an organization or across organizations and over time	<p>Example: Measure can be used reliably in multiple studies.</p> <p>Hong AL, Sawyer MD, Shore A, et al. Decreasing central-line-associated bloodstream infections in Connecticut intensive care units. <i>J Healthc Qual</i> 2013;35(5):78–87.</p>
Measure is valid	Measure will capture what it was <i>intended</i> to measure	<p>Example: Measure of CLABSI is capturing true infection rather than colonization. Standardized audit process for validation.</p> <p>Hazamy PA, Van Antwerpen C, Tserenpuntsag B, et al. Trends in validity of central line-associated bloodstream infection surveillance data, New York State, 2007–2010. <i>Am J Infect Control</i> 2013;41(12):1200–1204.</p>
Can be interpreted	Measure is easily understood by users of the data (e.g., staff, leaders)	<p>Example: Feedback to staff about hand hygiene compliance, device-related infections; staff understand the data and can apply it to their work</p> <p>Kowitt B, Jefferson J, Mermel LA. Factors associated with hand hygiene compliance at a tertiary care teaching hospital. <i>Infect Control Hosp Epidemiol</i> 2013;34(11):1146–1152.</p>
Risk-adjusted or stratified	Data are stratified by factors that take into account differences within a group that influence comparisons; used in benchmarking	<p>Example: Stratifying neonates by grams of weight at birth and infection risk:</p> <p>Centers for Disease Control and Prevention (CDC). Key Terms. CDC website. 2014. Available at: <a href="http://www.cdc.gov/nhsn/PDFs/pscManual/16PSCkeyterms_current.pdf">http://www.cdc.gov/nhsn/PDFs/pscManual/16PSCkeyterms_current.pdf</a>.</p> <p>Stratifying SSI: Magill SS, Klompas M, Balk R, et al. Developing a new national approach to surveillance for ventilator-associated events: Executive summary. <i>Am J Infect Control</i> 2013;41:1096–1099.</p>
Data collection methods	Availability and accessibility of required data elements; method and cost of collecting data; interpretation of collections methods	<p>Example: Obtaining surveillance data for central line or indwelling urinary catheter days using computerized medical record data, data mining, or well-designed and tested methodology</p> <p>Brossette SE, Hymel PA Jr. Data mining and infection control. <i>Clin Lab Med</i> 2008;28(1):119–126.</p> <p>Centers for Disease Control and Prevention (CDC). Patient safety component training. CDC website. 2013. Available at: <a href="http://www.cdc.gov/nhsn/Training/patient-safety-component/">http://www.cdc.gov/nhsn/Training/patient-safety-component/</a>.</p>

Under  
provider  
control

Evidence that the measure addresses processes or outcomes over which the healthcare organization has responsibility, control, and the ability to effect change

Example: Compliance with isolation procedures, application of "bundles" for preventing surgical site infections; transmission of multidrug-resistant organisms within the facility

Institute for Healthcare Improvement (IHI). Home page. IHI website. 2014. Available at: <http://www.ihl.org>.

Accountability Measures:

The Joint Commission (TJC). Accountability measures. TJC website. 2014. Available at:

[http://www.jointcommission.org/accountability\\_measures.aspx](http://www.jointcommission.org/accountability_measures.aspx).

## Developing Performance Measures

If reliable and valid performance measures do not already exist to meet the infection prevention and control program's specific purpose, it may be necessary to develop a new measure or measure set. Characteristics requiring attention include most of those described in TJC's outline of *Attributes of Core Measures and Associated Evaluation Criteria* (Table 17-1). Several of these criteria are discussed here.

### *DEFINING AND COMPARING THE EVENT OF INTEREST AND POPULATIONS*

The event of interest and the population to be assessed must be explicitly defined. For example, infections in a surgical orthopedic population of total joint replacements should be characterized as primary or secondary replacements to more precisely consider infections related to the different risks associated with these procedures.

In addition to understanding the patient characteristics that may affect the measure's rate, the plan for comparative analysis is also an important factor when determining the population of interest and approach to adjustment (stratification or statistical risk adjustment). If the plan is to compare across organizations or types of patients, the more robust approach to risk adjustment may be indicated because comparison may be misleading without appropriate adjustment.<sup>50,54</sup> This has emerged as a challenge in the public reporting of infection rates by hospitals within a single state and by states across the country as well as in nationwide surveys.<sup>55</sup>

### *DEFINING DATA ELEMENTS AND DATA COLLECTION*

Performance measures consist of data elements required to identify the event and population of interest. To be useful, performance measures must be amenable to a reliable and reproducible collection method. *Reliability* is "the ability of the indicator to accurately and consistently identify the events it was designed to identify across multiple healthcare settings."<sup>37</sup> *Reproducibility* evaluates whether the findings can be repeated consistently when applied to new populations, to different institutions, or by different individuals.<sup>17</sup>

Collection methods should have a high degree of interrater reliability, which means at least two raters reviewing the same set of information could consistently classify the performance measure in the same way. For example, two members of the infection prevention team reviewing VAP using the same criteria should have a match on designation as HAI most of the time. Any new data collection method should be tested. A recommended process includes a data collection template, tested on a sample of charts (10 to 30 is reasonable), then application of the methodology. It is important to build in regular reevaluation intervals to allow the tool or method to be revised to support accurate data collection. Another process might be to build in regular re-audits by impartial auditors or collectors. An infection preventionist group

might bring charts to a central meeting and pass the charts around the room to infection preventionists from another facility for review to determine if the same data can be abstracted.

To drive reliability and validity, definitions and data collection procedures need to be agreed upon in writing, with sufficient detail to support consistent methods, whether for one or numerous data collectors.<sup>27</sup> For example, as part of TJC's core measure set, a data element that is captured for many patients is *point of origin for admission or visit*. The data element is defined as "a code indicating the point of patient origin for this admission."<sup>18</sup> To assist the data collector in understanding the data element, there is a suggested data collection question: "What was the point of origin for this admission?" Allowable values are provided to note where the patient came from prior to inpatient admission (e.g., home, emergency department, transfer from a long-term care or another acute care facility, etc.). Another example is birth weight; documented birth weight can vary from the delivery room, to nursery admission, to other locations noted in the first 24 hours of life. When this is the case, guidance must be provided about which data source to use for the data element value. The NHSN criteria are used throughout the world as clear and consistent definitions to collect valid and reliable information. Through years of experience and testing of performance measures in hundreds of hospitals, healthcare measurement experts have come to realize that this level of detail is essential for reliable and valid measurement.

#### *TIMELINESS OF DATA COLLECTION AND REPORTS*

Data are most useful when the time between data collection and reporting is short. In terms of intrahospital use, rapid analysis of data is key to the ability to identify opportunities for improvement. Generation of timely internal reports is important to the function of supplying data useful to clinicians. The concept of "report cards" has gained popularity because leadership decides which performance measures need to be collected in "real time" and presented daily, weekly, or monthly. Also important is the ability of the individual organization to generate its own analyses from data collected for the indicator system; this may require that centrally distributed software has ad hoc reporting capabilities or, at the least, generates data files of a known and standard format. The rapid reporting of data to an aggregating agency can assist in ensuring completeness of the overall database.

#### *ACCURACY AND COMPLETENESS OF DATA COLLECTION*

Equally important to reliability and accuracy of the collected data is the *completeness* of data collection. Every system should have explicit written descriptions of data collection methods that minimize ad hoc, off-the-cuff decisions. Staff who will be collecting data will use these instructions and should receive training on data collection methods. Ideally, training data collection personnel should include the opportunity to practice data abstraction, chart review, data entry, and the like, as well as to provide feedback on performance. Training is a critical aspect of ensuring the reliability and reproducibility of future data. Infection surveillance intensity must be consistent if data are to be compared over time or among institutions. The NHSN now provides intensive training courses in person and online for those using their surveillance systems.<sup>56,57</sup>

Factors to consider are the frequency and reliability of collected data, staff involved, and data sources. Are you collecting prevalence or incidence data? Are you collecting data using the same staff members or are multiple staff members involved? Are data collected the same way when the facility has suboptimal staffing or absences of the data collection personnel? Treating data collection as a low-priority activity may result in retrospective chart reviews when concurrent data collection is the preferred method. Inadequate computer, programmer, and data input staff resources and incomplete chart information or availability also may affect the completeness and accuracy. In addition, data gleaned from



computer databases can be significantly affected by new coding staff and a different level of education or experience.

### *FEASIBILITY AND EASE OF DATA COLLECTION*

For broad application, data elements must be amenable to accurate and consistent collection. Benefits gained or lost by adding or deleting specific elements must be weighed carefully. The evaluation of benefit should reflect the likelihood that the additional information will assist in clinical decision making and, ultimately, in improved outcomes. Limited resources ordinarily would be directed toward the following issues: (1) which documentation exists that correlates data collection and reporting with improved outcomes, (2) which has the greatest theoretic potential for improvement, or (3) which can reveal the most grave consequences.<sup>17</sup> Human resources, staffing needs, data collection, and analysis of personnel hours should also be considered. Table 17-3 lists important questions to ask prior to data collection.

**Table 17-3** Questions to Ask Regarding Data Collection

- Who may already have these data?
- Who already has a need to review this record (e.g., other departments, services, individuals)?
- If others have collected data, what are their criteria and methodology?
- Are the data collected reliable and valid?
- Who reviews the data before it is finalized?
- What database(s) exist that could provide a framework to build on (e.g., admission, discharge, transfer [ADT], mortality, financial)?

Frequently after asking these questions, researchers, infection preventionists, or quality staff may find that they can "piggyback" to an existing data collection process or data set.

## Using Data to Drive Improvement

Providers and users of infection prevention data must be fully knowledgeable about sound epidemiological principles that apply to the use and development of performance measures. They must also be aware of the perils if these principles are ignored or not fully employed in the design, collection, aggregation, and analysis of data.

### Internal Tracking Versus External Comparisons

Once an indicator has been determined to be appropriate for comparing healthcare practices within an institution, the decision as to whether it is appropriate for comparing results at two or more institutions needs to be made. Gray's book *Evidenced-Based Healthcare* provides excellent guidelines on how to benchmark, develop, and use outcome measures.<sup>58</sup> An indicator always should be validated before any new use, particularly for comparisons with external sites. The data collection concepts discussed here are important to reassess as data are compared across facilities. Are the data collected using the same methodologies, level of training, database, and chart reviews? Are the data collected concurrently or retrospectively? When attempting to compare infection rates across organizations, such as in collaboratives to reduce central line- or ventilator-associated infections, the participants must agree as to the indicator and the methods and intensity of the data collection process.<sup>58</sup>

Before using a reported indicator rate as a benchmark, it is critical to know whether the setting and data collection techniques are comparable. For example, was surveillance at the benchmarking institution

comparable to that of the other institutions? Are the definitions of disease and risk comparable? Given that true benchmarking requires knowing who is "best in class" for a given outcome or process, one needs to be able to determine who the "best" is so they can be used as a resource to improve care. Most comparative databases do not identify the reporting institutions so that true benchmarking is not possible. Usually, results at an organization are simply compared with the range of results reported by similar institutions. For example, in the NHSN database, the identities of the reporting organizations are not revealed; however, collaboratives are often more transparent.

Appropriate statistical testing should be part of both internal and external comparison exercises. This is critical, especially when comparative data are used in the process of credentialing and privileging individual practitioners or in institutional accreditation. In addition, accurate analysis of data can ensure that resources are directed toward clinically important issues.<sup>4</sup>

## Relation to Quality Improvement and Patient Safety: Using Performance Measures

Accurate indicator data that include HAIs can be useful and supportive of quality improvement and patient safety efforts within an organization. In the performance improvement paradigm, clinical decisions are based on data that are gathered and analyzed over time using appropriate statistical tools and feedback to clinicians. These improvement efforts can address both endemic levels of disease (as common-cause variation), as well as epidemic levels of disease (as special cause variation). Good epidemiology is as important for use of data internally as it is for external comparisons.<sup>4</sup>

As institutions aggregate surveillance data on HAI rates to use for interhospital or interorganizational comparisons, debate among healthcare epidemiologists, infection prevention professionals, and quality staff continues as to which indicators best reflect true quality.<sup>59</sup> At the time of the publication of the QI Study Group findings, participation in a multihospital surveillance system was not as common as it is now. For example, the facilities that hold TJC accreditation status are now required to select indicators and collect and submit their data per TJC requirements. CMS recently launched its Nursing Home Compare website<sup>60</sup> to provide consumers with rates on many indicators that reflect the overall quality of nursing homes and skilled care centers in their communities. CMS is also beginning data collection for the National Voluntary Hospital Reporting Initiative.<sup>61</sup>

The decision to participate in performance measurement is no longer optional. The decision to be made is which indicators and measurement methods to use and how to turn the data into action that will improve patient care and safety. These decisions should be discussed at all levels of the organization, from senior management to frontline caregivers. There must be a strong link between the collection of infection data and the organization's continuous improvement strategy and support of clinical teams' use of data to improve the quality of healthcare.

## Conclusions

This chapter provides a historical overview of the development and use of performance indicators in infection prevention. The authors identify the many performance improvement measures and systems in use and present concepts and guidelines for evaluating and selecting existing indicators and considerations for creating new ones. The use of performance indicators in healthcare and infection prevention in particular is essential to improve patient safety and quality. Existing indicator systems are in a constant state of flux and development so that producing a listing comparing current systems would



be difficult, if not impossible. However, the NHSN system is well developed, continues to be refined and expanded, and provides excellent guidance for infection preventionists. Quality improvement report cards for the evaluation of outpatient, home health, long-term, and managed care systems have recently been deployed and can provide good examples for infection preventionists wanting to refine and enhance their system of monitoring.

## Supplemental Resources

Centers for Disease Control and Prevention (CDC). *National Healthcare Safety Network Training*. CDC website. 2013. Available at: <http://www.cdc.gov/nhsn/training/>.

Centers for Medicare & Medicaid Services (CMS). *Hospital quality measures submitted voluntarily by hospitals*. CMS website. 2013. Available at: <http://www.hospitalcompare.gov>.

Centers for Medicare & Medicaid Services (CMS). *Nursing home compare*. Medicare.gov website. 2013. Available at: <http://www.medicare.gov>.

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## Patient Safety

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### Abstract

*"If you know how to prevent infections, you know how to protect patients from most adverse events."<sup>1</sup>*

*The patient safety movement in this country is thought to have begun in 1999, with the publication of the Institute of Medicine's report To Err is Human.<sup>1</sup> In fact, formal efforts to keep patients safe began in the United States with the development of hospital infection prevention and control programs in the 1960s, and globally, even as far back as the mid-1800s, when Hungarian physician Ignaz Semmelweis and British nurse Florence Nightingale publicized the value of hand hygiene as an infection prevention technique. Currently, between 5 and 10 percent of patients admitted to acute care hospitals acquire one or more infections, representing the most common adverse event affecting approximately 2 million patients each year in the United States. It is estimated that 90,000 deaths and an estimated \$33 billion per year reflect the healthcare burden of these complications.<sup>2,3,4</sup> These data demonstrate the critical link between infection prevention and control and improving patient safety.*

*Although the statistics on medical errors have been widely scrutinized, one cannot cast a blind eye to the additional 50,000 to 100,000 deaths annually caused by medication errors, falls, wrong site surgeries, missed diagnoses, or misidentified patients. There has been a public outcry and a national call to action to address this epidemic and focus on preventing all healthcare-related adverse events. Every healthcare professional, at every level, and across all healthcare settings, has been challenged to develop and implement programs to actively seek out risk and document harm (surveillance/reporting), to proactively design standardized processes and systems (prevention), and to create a culture where everyone with every action is responsible and accountable for patient safety (control). This chapter*

*provides an overview of surveillance and disease prevention and control of the broader patient safety challenges and their role in national patient safety efforts.*

## Key Concepts

- Patient safety science draws methods from high-risk industries such as aviation and nuclear power. The primary purpose of the terminology review is to define safety principles and create shared language among professionals in infection prevention and control.
- An understanding of James Reason's theory on organizational accident causation improves sensitivity to latent holes within the healthcare system and development of safeguards.
- The infection preventionist should have an appreciation for systems-thinking and awareness of concepts such as human factors engineering and how the human interacts with the system.
- Blending evidence-based epidemiologic strategies and clinical knowledge with the human capital will contribute to an organization's culture of safety.
- Enhancing surveillance for patient safety events including a nonpunitive response to patient safety event reporting is essential for the detection of near miss and precursor safety events.
- An understanding of error wisdom will assist the infection preventionist in defining strategies to mitigate error based on error type thereby strengthening system design.
- The infection preventionist is an integral part of quality initiatives and becoming familiar with patient safety language will help facilitate interventions as infection preventionists partner with a variety of disciplines and colleagues on designing safe, reliable systems to support infection prevention and control.

## Background

The Institute of Medicine (IOM) defines medical error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.<sup>1</sup> The internationally recognized patient safety leader of the modern patient safety movement Dr. Lucian Leape, in his hallmark study, researched and analyzed data from more than 30,000 hospitalized patients in New York state and found that 3.7 percent of inpatient admissions experienced an adverse events (see Figure 18-1). The Committee on the Quality of Health Care in America was established in 1998 by the IOM and its first report, *To Err is Human*, estimated that between 44,000 and 98,000 Americans die each year as a result of medical mistakes with an associated cost of \$17 to \$29 billion.<sup>1</sup>

### Figure 18-1.

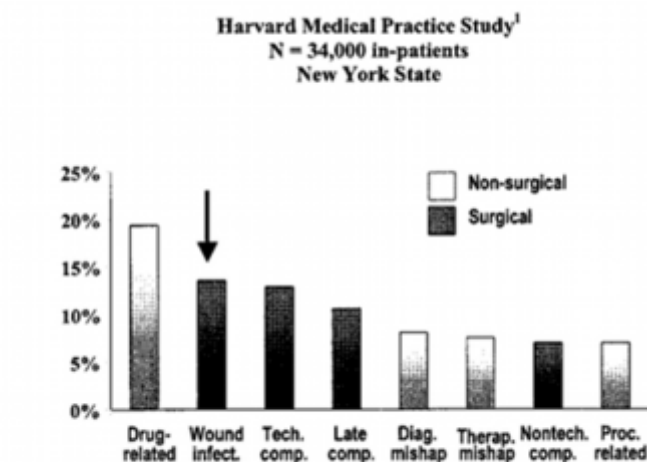
Most frequent adverse events in hospitalized patients.

[View Image](#)



The report prompted examination of the "human" aspect of error, specifically to look at faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them from doing so. This signified a move away from a more traditional medical and nursing school model that looked to blame mistakes on individuals, their lack of adequate training, or their lack of compliance with policy or procedure, which may indeed be inadequate or error-prone. The most common adverse errors affecting patients include: medication and transfusion errors, infections, complications of surgery (including wrong-site surgery), suicide, restraint-related injuries, falls, burns, pressure ulcers, misidentification, and wrong





Source: Brennan, 1991

Inadequate policies and procedures

diagnosis or treatment.

The Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) summarizes the underlying causes of medical errors to be related to:

- Communication problems
- Inadequate information flow
- Human problems
- Patient-related issues
- Organizational transfer of knowledge
- Staffing patterns/work flow
- Technical failures
- 

Reported medical error-related deaths exceed the combined numbers of deaths and injuries from motor and air crashes, suicides, falls, poisoning, and drownings, despite the fact that such events are still seriously underreported. Most reported errors occur in intensive care units, operating rooms, and emergency departments. In addition to the high cost in morbidity and mortality linked to medical errors, AHRQ estimates that medical errors cost a large hospital about \$5 million per year and total \$17 to \$29 billion per year in the United States.<sup>7</sup> Costs include the expense of additional care required to treat medical errors, lost income and household productivity, and the cost of long-term or permanent disability. Encinosa and Hellinger<sup>8</sup> studied 14 AHRQ Patient Safety Indicators (PSIs) for more than 160,000 surgeries and found 90-day costs for surgeries with PSIs to be \$66,879 on average versus \$18,284 for surgeries without PSIs. Furthermore, surgeries with preventable infections had 2.6 times higher odds of death than surgeries without such infections. An excessive readmission rate was also demonstrated for postoperative patients who suffered a PSI.<sup>8</sup>

Potentially preventable medical errors that occur during or after surgery alone may cost employers nearly \$1.5 billion per year, according to new estimates by AHRQ. A reduction in medical errors could result in large cost-savings for healthcare organizations as well as for purchasers/insurers. The ability to articulate a compelling business case for the avoidance of these adverse events may prompt system-wide investments in infection prevention and patient safety.<sup>9</sup>

The Centers for Disease Control and Prevention (CDC) estimates that 2 million patients per year develop infections in U.S. hospitals and that approximately 90,000 die (1 death every 6 minutes).<sup>10</sup> The Harvard Medical Practice study listed surgical site infections (SSIs) as the second most common adverse event experienced by inpatients in New York hospitals.<sup>11</sup> The literature reports that up to 350,000 hospitalized patients acquire bloodstream infections each year, and these infections cost a minimum of \$38,703 per episode.<sup>12</sup> Bloodstream infections are associated with a mean attributable mortality of 15 to 20 percent.<sup>13</sup> The impact of these two types of healthcare-associated infections (HAIs) alone underscores the importance of infection prevention in reducing adverse outcomes from hospitalization. Nearly 70 percent of HAIs are due to microorganisms that are multidrug resistant,

indicating an escalating public health crisis.<sup>14</sup> Furthermore, the infection-related PSIs have the highest excess postdischarge costs including readmission.<sup>8</sup>

Oversight by regulatory and accrediting agencies such as The Joint Commission (TJC) have generated a reported data set of sentinel events. TJC encourages voluntary reporting of sentinel events and requires that a root cause analysis (RCA) be conducted and results with the accompanying action plan be reported. Between 1995 and 2012, 6,994 sentinel events have been reported to TJC, 59.9 percent of which resulted in patient deaths.<sup>15</sup>

Now, more than 14 years after the original IOM report, patient safety error rates remain high despite modest improvements in overall healthcare quality. The urgency to improve remains as critically important now as when the report was first published.

## Basic Principles

The national attention galvanized by the IOM report has resulted in notable patient safety trends. One such trend is the effort to encourage, and in some instances mandate, public reporting of patient safety adverse events within a healthcare setting. Efforts to establish a common patient safety taxonomy are consistent with the public reporting effort.

The collection, aggregation, and analysis of patient safety data are essential to improving patient safety. These data must be used for further analysis and research and as a guide to the design of safer systems of care. Many government and private entities collect and evaluate such data including federal and state agencies, national accrediting and certifying bodies, professional organizations, insurance companies, and individual healthcare delivery systems. A standardized framework for classifying patient safety data was coordinated by AHRQ in collaboration with the National Quality Forum (NQF) and the Federal Patient Safety Workgroup (PSWG) that resulted in the development of Common Formats for the voluntary reporting of safety events to patient safety organizations (PSOs). Sharing of event data is authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule). The Patient Safety Rule established a framework for PSOs to facilitate the sharing of safety information in a confidential, protected manner without fear of legal discovery. Several states and professional organizations also have PSOs; however, every entity must certify with AHRQ to comply with the patient safety activities specified in the Patient Safety Rule.

Until recently, the lack of a universal framework was a major barrier to the systematic understanding of where and how these adverse events occur, and most importantly, how to prevent them. The term "Common Formats" refers to a conceptual framework, definitions, and reporting formats that allow standardized submission of patient safety data including incidents, near misses, or unsafe conditions.<sup>16</sup>

The Patient Safety Event Taxonomy (PSET) developed by TJC with the assistance of representatives of provider and health professional organizations and the federal government, contains five complementary root nodes, or primary classifications:<sup>17</sup>

1. Impact: the outcomes or effects of medical error and systems failure, commonly referred to as harm to the patient
2. Type: the implied or visible processes that were faulty or failed

3. Domain: the characteristics of the setting in which an incident occurred and the type of individuals involved
4. Cause: the factors and agents that led to an incident
5. Prevention and mitigation: the measures taken or proposed to reduce the incidence and effects of adverse occurrences

The development and maturation of a patient safety taxonomy, PSO protection, and the advancement of public reporting of adverse events are complementary and important byproducts of the IOM report.

Public reporting should serve multiple purposes including establishing public accountability for healthcare providers, use of these data by consumers and purchasers in choosing healthcare providers, and supporting quality improvement by providers. To date, public reporting has stimulated patient safety and quality improvement activities by providers in response to the availability of facility-specific performance along with specific process and outcome measures.

A dramatic example of public reporting of adverse events and the link to pay-for-performance is Section 5001(c) of the Deficit Reduction Act of 2005 that requires the identification of conditions that: (1) are high-cost or high-volume, or both; (2) result in the assignment of a case to a diagnosis-related group (DRG) that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.<sup>18</sup> Therefore, for discharges occurring on or after October 1, 2008, hospitals do not receive additional payment for cases in which one of the selected conditions was not present on admission. According to the Centers for Medicare & Medicaid Services (CMS), hospital-acquired conditions (HACs) are conditions CMS deems to be reasonably preventable with the implementation of evidence-based guidelines. The policy aims to provide hospitals with a financial incentive to improve patient safety as measured by the occurrence of these adverse events.

Beginning July 2008, CMS included 10 conditions that were selected for the HAC payment regulations. The 10 categories of HACs are:

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Stage III and IV Pressure Ulcers
5. Falls and Trauma:
  - Fractures
  - Dislocations
  - Intracranial Injuries
  - Crushing Injuries
  - Burns
  - Electric Shock
6. Manifestations of Poor Glycemic Control:
  - Diabetic Ketoacidosis
  - Nonketotic Hyperosmolar Coma
  - Hypoglycemic Coma
  - Secondary Diabetes with Ketoacidosis
  - Secondary Diabetes with Hyperosmolarity

7. Catheter-Associated Urinary Tract Infection (UTI)
8. Vascular Catheter-Associated Infection
9. Surgical Site Infection Following:
  - Coronary Artery Bypass Graft (CABG) - Mediastinitis
  - Bariatric Surgery
  - Laparoscopic Gastric Bypass
  - Gastroenterostomy
  - Laparoscopic Gastric Restrictive Surgery
  - Orthopedic Procedures: Spine, neck, shoulder, elbow
10. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE):
  - Total Knee Replacement
  - Hip Replacement

Of note, three of these 10 HACs are directly related to infection prevention and control efforts. This public reporting and pay-for-performance is intended to accelerate improvements in patient safety, although the early published analyses have identified that the effect of these policies remains unclear.<sup>19</sup>

## Patient Safety

### Creating a Culture of Safety

Theories and models about patient safety raise awareness about the complexity of the system where patients receive care and providers work. The patient safety literature is filled with recommendations for organizational leaders to become "systems thinkers" and to eliminate the "blame-and-shame" mentality of the past. A culture of safety must prevent punitive reactions to mistakes, and staff members must feel confident that if they speak out about risk, their leaders will respond. Providers involved in medical errors must know that leaders will look beyond the obvious and drill down until the root causes of accidents and errors are found and that they will routinely evaluate systems and processes during any accident investigation. Until such a major culture change is embraced and frontline staff members are more involved in the decision making that affects the delivery of care, we will never get to the true etiology of medical errors, and our efforts at prevention and elimination may be futile.

Before we can envision a culture of safety, we must understand the culture of complex organizations. Organizational culture can be described as the set of values, guiding beliefs, or ways of thinking that are shared among members of an organization. It is the feel of an organization that is quickly picked up by new members. Culture is "the way we do things around here." Culture is powerful and is perhaps most noticeable when new strategies or programs are implemented that go against the embedded organizational culture.

Schools of medicine, nursing, and allied health previously taught providers to ask when things went wrong: "Who did it?" The focus was on individuals' failures. During a testimony before Congress in December 1999, discussing human error management, Dr. Lucian Leape stated, "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes."<sup>20</sup>

Leaders are obliged to discover where systems broke down, leaving both patients and staff at risk for accidents and errors and to ask, "What happened?" The traditional culture reacts to harm after it

occurs. In a safety culture, we try to anticipate accidents and errors and to be proactive and identify risks before they result in harm.

A punitive culture reacts to bad behaviors; a just culture looks at the system: the environment, the knowledge, the tools, and other stressors that may affect behavior. In a just culture, top-down communication is replaced with bidirectional communication with information flowing down to the front line from leadership and back up to leadership from those providing patient care on the front line. Silence about harmful events is discouraged. Instead, open, honest disclosure about serious patient safety events builds a learning organization and a safer place to work and provide care.

### *CREATING, MAINTAINING, AND MEASURING A SAFETY CULTURE*

The creation, maintenance, and periodic measurement of a culture of safety are now health system regulatory requirements. As healthcare organizations continually strive to improve, there is a growing recognition of the importance of establishing a culture of safety within which clinicians work and patients receive care. Achieving a culture of safety requires an understanding of the values, beliefs, and norms about what is important in an organization and what attitudes and behaviors related to patient safety are expected and appropriate. Various safety culture measurement tools have been developed including: the AHRQ Hospital Survey on Patient Safety Culture; the AHRQ Medical Office Survey on Patient Safety; and the Safety Attitudes Questionnaire (SAQ).<sup>21,22</sup>

Healthcare organizations can use these survey assessment tools to:

- Assess their patient safety culture
- Track changes in patient safety over time
- Evaluate the impact of patient safety interventions

The AHRQ shares benchmark safety culture data, which allows a healthcare organization to evaluate their performance against peers and over time.

A healthcare setting with a strong safety culture has been described as generative, uneasy about risk, constantly seeking out best practices, always looking for where the next mistake is going to happen, and then working to prevent it. A safety culture fosters a "learning organization," where staff members share information about mistakes and errors in order to prevent them from recurring. This type of organization emphasizes reciprocal accountability, meaning that everyone holds each other accountable for patient safety. The leadership can expect staff members to call out or stop the line when they see risk, and staff can expect leadership to listen and act, even if that involves dealing with problem professionals who display intentionally reckless behaviors. Patients and family members must be included as respected partners and must understand their own responsibility for keeping themselves safe.

The National Patient Safety Foundation outlines five attributes of a safety culture that all healthcare organizations should strive to operationalize through implementation of strong safety management systems:<sup>23</sup>

1. All workers (including frontline staff, physicians, and administrators) accept responsibility for the safety of themselves, their coworkers, patients, and visitors.
2. Safety has priority over financial and operational goals.
3. The organization encourages and rewards the identification, communication, and resolution of safety issues.
4. There are provisions for organizational learning from accidents.

5. The organization allocates appropriate resources, structure, and accountability to maintain effective safety systems.

## Human Factors and Patient Safety

Patient safety programs are beginning to take advantage of tools that have been used in industry and manufacturing for years to study the cause and effects of human error. Five tools—such as, human factors engineering, human factors analysis, ergonomics, error wisdom, and reliability science—represent examples of this effort.<sup>24</sup>

- Human factors engineering (HFE) involves research in human psychological, social, physical, and biological characteristics and is concerned with design of tools, machines, and systems that take into account human capabilities, limitations, and characteristics. The goal is to create designs that are safe, comfortable, and effective for humans to use.
- Human factors analysis is the systematic study of elements involving a human-machine interface with the intent of improving working conditions or operations.
- Ergonomics is the science of studying people at work, then designing tasks, jobs, information, tools, equipment, facilities, and the working environment so that people can be safe, effective, productive, and comfortable. In the highly complex healthcare environment, understanding how humans interface with technology and equipment is crucial to understanding and preventing errors. Error wisdom recognizes that complex, high technology systems are subject to rare but usually catastrophic organizational accidents in which a variety of contributing factors combine to breach the many safeguards and that some organizational accident sequences could be thwarted at the last minute if those on the frontline had acquired some degree of mindfulness about failure points.<sup>25</sup>
- Reliability science is the study of a process to achieve "failure-free" operation over time to reduce process defects and improve system safety.
- Resiliency is the intrinsic ability of a system to adjust and sustain operations during periods of stress or after an event.

The concepts associated with HFE can help healthcare personnel, especially those involved with patient safety, to analyze events and develop workable and effective countermeasures, eliminating the use of dangerous shortcuts that lead to medical errors.<sup>26</sup> Safety leader James Reason believes that humans are fallible and errors are to be expected, even in the best organizations. People naturally automate tasks to conserve mental energy and because automatic activity often has predictable outcomes.<sup>27</sup> Building on the concepts of error wisdom, the infection preventionist (IP) can strengthen the design and compliance of prevention strategies.

Reason describes three error types: skill based, rule based, and knowledge based (Table 18-1). Slips and lapses are examples of skill-based errors. A slip is an external failure in a plan due to reduced intentionality, whereas a lapse is an internal failure occurring from failures of memory and memory storage. Rule-based errors occur when the action is in response to how we were taught.<sup>28</sup> When someone does not recognize a contraindication, the provider may have misapplied a seemingly good rule. Past experiences, training, or misunderstanding can result in the development and execution of bad or misapplied rules. Finally, knowledge-based decision making requires the highest cognitive level and is highly prone to error. These types of errors tend to occur when an individual is confronted with a new situation where it may not be evident what is unknown.



A well-known definition of reliable is giving the same result on successive trials; however, the same results are not necessarily the correct result. The Institute of Healthcare Improvement (IHI) and David Garvin at the Harvard Business School define reliability in healthcare as "failure free operation over time" and that the reliability can be calculated as the inverse of the failure or defect rate.<sup>29</sup> For example, the time an antibiotic fails is 1 in 10 so the reliability would be 90 percent. Drawing on lessons learned from diverse and high-hazard organizations, authors of *Managing the Unexpected*, Karl Weick and Kathleen Sutcliffe, identified five attributes of high-reliability organizations that result in a collective mindfulness and enactment: preoccupation with failure, sensitivity to operations, reluctance to simplify, commitment to resilience, and deference to expertise.<sup>30</sup> Used in concert with the science of epidemiology, these five principles may be demonstrated as:

**Preoccupation with failure**— maintain sensitivity for the early signs of failure. *What might contribute to staff not being able to follow a protocol or isolation procedure?*

**Sensitivity to operations**— awareness of changes in the dynamic and nonlinear systems. *What types of cases are coming into the organization or what community activity might impact our resources and ability to provide care?*

**Reluctance to simplify**— understanding that labels may impede further evaluation and appreciating the value of diverse perspectives. *How might I involve multiple departments or conduct an interdisciplinary review of infection prevention practices to ensure what makes sense from an infection prevention perspective can be operationalized within the healthcare organization?*

**Commitment to resilience**— ability to absorb acute or chronic stress and adjust to sustain operations. *How might I quickly identify and contain outbreak (e.g., identify cluster of events, quickly evaluate practices, handling of equipment, and isolation procedures)?*

**Deference to expertise**— mutual recognition of knowledge or expertise of those in all organizational levels. *Contacting an IP for an uncommon clinical situation or using local experts to understand a population and coinciding processes.*

**Table 18-1.** Error Wisdom and Mitigating Strategies Based on Error Type<sup>28</sup>

**Table 18-1** Error Wisdom and Mitigating Strategies Based on Error Type

Cognitive Level	Activity	Error Type	Example	Error Wisdom	Wisdom to Practice
Skill based	*Automatic  Medication administration, initiating tube feeding, obtaining blood samples	Slip	Inadvertent misconnection of enteral feeding tubing to an intravenous port	The most automatic and reflexive tasks are susceptible. Contributing factors are environmental (noise, hostile work environment) and individual (fatigue).	Conscious reconciliation of connections, 2-person independent verifications
Lapse	Forgetting to stop an insulin infusion after stopping tube feeding	Resist multitasking, develop checklists			



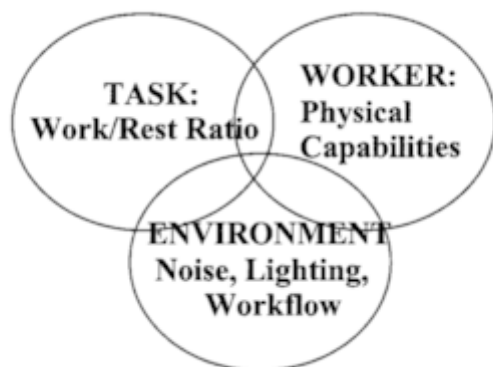
Rule based	<i>Everyday problems addressed with relative ease</i>	Rule-based mistake	Administration of insulin aspart in the arm instead of the abdomen (applying the rule "if administering insulin, then the arm is an option")	Good rules fail when we fail to spot either relative of absolute contraindications. Bad rules may be developed on the basis of experience or training.	Engage in metacognition: Ask yourself, "What else must I know before I apply this rule?" or "Am I assuming something about this situation?"
	Algorithms, practice guidelines				
Knowledge based	<i>Deliberate conscious problem solving</i>	Knowledge-based mistake	A nurse is caring for a pregnant patient with vaginal bleeding. Unaccustomed to such patients, the nurse decides after much deliberation to perform a digital examination, tearing the placenta.	Confirmation bias (the tendency to find information to support our hypothesis, and to ignore information that does not) is common in this setting.	Engage in metacognition: Deanchor from the problem, evaluate the characteristics of self, task, and environment, seek to mitigate them and activate deliberate strategies to reduce error.
	Clinical decision making, complex management decisions				

Ideally, those analyzing critical or sentinel events are also working on proactively identifying risk and putting measures in place to prevent recurring mistakes. When planning to bring new technology or equipment to the patient care setting, or when evaluating work flow, there are several questions one should ask about the expectations of the operator (human), the tools and equipment, and the environment in which the operator is expected to function. When conducting a human factors analysis relating to patient safety, Carayon and colleagues recommend including the following questions:<sup>31</sup>

- What are the characteristics of the individual performing the work? Does the individual have the musculoskeletal, sensory, and cognitive abilities to do the required tasks? If not, can any of these gaps in ability be accommodated in the design of the task?
- What tasks are being performed, and what characteristics of those tasks may contribute to unsafe patient care? What in the nature of the tasks allows the individual to perform them safely or assume risks in the process?
- What tools and technologies are being used to perform the tasks, and do they increase or decrease the likelihood of untoward events?
- What aspects of the physical environment can be sources of error or promote safety? What in the physical environment ensures safe behavior or allows room for unsafe behavior?
- What in the organization prevents or allows exposures to hazard, and what promotes or hinders patient safety? What allows for assuming safe or unsafe behavior by the individual?
- Components of human factors assessment should also include:
  - Evaluating the work: What is the work/rest ratio?
  - Evaluating the workers: What are their physical and mental capabilities?
  - Evaluating the environment: Do noise levels, lighting, and work flow inhibit or facilitate successful completion of the task? (See Figure 18-2.)

**Figure 18-2.**

Components of a human factors assessment. (From Wolf L. BJC HealthCare, Patient Safety Curriculum. Human Factors Module. 2004. Available through Barnes Jewish HealthCare.)



We all experience the interplay of [View Image](#) factors in our everyday lives. For example, we may encounter double doors on which the handles on each are made to pull the door open, despite the fact that one door opens in and should be pulled, and the other opens out and should be pushed. A good design makes actions of the user intuitive; there should be no need to apply signs or stickers to indicate proper usage or give instructions. Poor design in infection prevention may be when the product that is available does not meet the needs of the

end user. For example, when the size of single-dose vials is too large this may prompt providers to conserve medications using the vial multiple times to withdraw subsequent doses.

Human factor limitations that contribute to errors include:

- Limited memory capacity: five to seven pieces of information are typical for short-term memory
- Negative effects of stress and associated cognitive tunnel vision used to compensate and focus in highly intense situations
- Negative influence of fatigue and sensory overload
- Overdependence on multitasking skills of staff in complex work environments

When processes are designed without attention to human limitations, each individual employee interacting with the process will adapt the process in a nonstandard manner or create work arounds to complete the task.<sup>32</sup> The study of human factors helps us more easily identify and assess technology, equipment, systems, and processes that are (unintentionally) designed to allow mistakes. Conversely, understanding human factors helps us design forcing functions, making it harder to do the wrong thing. All healthcare personnel should be aware of the impact of human factors on reducing medical errors.

When evaluating a system one must understand the reliability of the system and the human using it. System reliability depends on the reliability of each individual component. Components can be in series, parallel, or in combination. Parallel systems are redundant and can increase reliability, as the human component in a system is the least reliable.

Pronovost and colleagues demonstrated the beneficial impact of a simple checklist to reduce catheter-associated bloodstream infection (CLABSI); a list of central catheter insertion process measures that should be completed to reduce the likelihood of the development of a CLABSI.<sup>33</sup> This redundancy allows healthcare clinicians a way to verify in real time that the intended evidence-based steps in a process were completed, thus ensuring standard work and leveraging capacity for complex cognitive action.

In healthcare, the patient is at the center of the system. Patient factors can include unique patient reactions (an intervention that works on one patient may not work on another) and unstable conditions within the same patient. For healthcare personnel, the mental workload involved in patient care is tremendous. A recent study looking at the working memory of a nurse indicates that he/she is thinking an average of 16 things simultaneously during a work shift, a process called cognitive stacking.<sup>34</sup> It is not hard to imagine errors of omission when the typical working memory holds a seven-digit telephone number without strain.

To illustrate the importance of the interface between human factors and the environment, consider the issue of clinical alarms as a safety measure. There are alarms on ventilators, cardiac monitors, intravenous pumps, and other equipment and computerized technology. Clinical alarms are designed to alert providers about danger, and slightly different sounds and pitches indicate need for an urgent, intermediate, or slower response. In a typical intensive care unit (ICU), it is easy to become desensitized to so many similar sounds, rhythms, and pitches. Unfortunately, alarms may simply become background noise with the result that a patient in real need may be overlooked for just a minute too long. Habituation to an alarm, or alarm fatigue, recently identified as a sentinel event alert (SEA) from TJC, is an extremely important phenomenon of which to be mindful.

Administrative and organizational issues are another component of the care-delivery system. Internal and external constraints and regulations have an impact on development of policies, procedures, and processes. Shift work is often associated with sleep deprivation and is also an SEA from TJC. Staffing levels are influenced by shortages of professional staff, budgetary constraints, and patient acuity.

*Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*, a December 2008 report from the IOM, asserts that revisions to medical residents' workloads and duty hours are necessary to better protect patients against fatigue-related errors and to enhance the learning environment for physicians in training.<sup>35</sup> The report recommended that residency programs provide regular opportunities for sleep each day and each week during resident training. In addition, it recommended that the Accreditation Council for Graduate Medical Education (ACGME) provides better monitoring of duty hour limits and that residency review committees set guidelines for residents' patient caseloads. Patient handover procedures and supervision of residents should also be strengthened. The recognition of the effect of fatigue on clinical performance, a human factors element, has resulted in this most recent effort to ensure patient safety and was refined again with the recent 2011 ACGME Duty Standards, which added more robust standards for ubiquitous practices such as moonlighting. The unintended consequence of this important safety initiative is more frequent patient handoffs, which may interfere with the continuity of care. This issue has been studied by Schuberth and Fornarow and warrants additional research into this concern.<sup>36,37</sup>

Communication may be the most important component of the patient-care system and is frequently cited as the root cause of TJC reported sentinel events. Communication about technology, equipment, processes, and procedures must be clearly delivered, and there must be confirmation that healthcare providers understand the message as it was intended. In an already complex environment, communications processes should be as simple as possible with little or no calculations required or opportunities for misinterpretation. In addition to verbal communication, visual cues (posters, signs, pictorials) can prompt redundancy and clarify steps in a process to ensure safety.

Patient safety experts and human factors engineers should work in partnership with manufacturers and distributors of medications. Since medication mishaps account for the majority of medical errors in most organizations, it is important to understand the dangers associated with look-alike and sound-alike medications. "TALL man lettering" on medication dispensing units and in storage areas is one human factors solution to a serious patient safety problem associated with look-alike/sound-alike (LASA) medications. TALL man lettering uses capital letters to distinguish the critical aspects of a particular drug name, leaving more generic aspects in lowercase.

Outcomes in complex work depend on the integration of individual, team, technical, and organizational factors. Using the traditional epidemiologic model (host, agent, and environment), the IP can be an

integral part of assessing systems and identifying situations where human factors problems are responsible for increased risk and helping to design the solution.

## Risk and Incident Reporting

If the current rate of harm in healthcare is to be reduced, how and why adverse events occur needs to be identified, and, in particular, how system defects may contribute to their occurrence. One way to do this is for individuals to report adverse events to organizations collecting, aggregating, and trending such data. The AHRQ defines near miss as "events in which the unwanted consequences were prevented because there was a recovery by planned or unplanned identification and correction of the failure." The effectiveness of a patient safety program can, to some degree, be measured by increased near-miss reporting, and employees openly admitting to mistakes and identifying broken systems before they result in patient harm.

Similar to surveillance for HAIs, especially post-discharge surveillance programs, adverse event or incident reporting can only be as effective as providers' willingness to report. The organization must set the expectation upon hire that safety event reporting is a priority. Individual employees have a responsibility to know and follow policies and procedures applicable to assigned duties, to use sound judgment and be aware of potential hazards before taking action, and to promptly report events or situations of actual or *potential* harm.

Management has a set of responsibilities that include educating staff on event reporting, making continuous safety improvements, and identifying system flaws and potential corrective actions. Managers must focus on the "how," not the "who" of an event while underscoring individual accountability and responsibility. This is the foundation of a just culture of safety. Individual performance as well as process and systems evaluations are critical to ensure safe practice. Hiring managers must make clear the expectations about patient safety responsibilities, asking employees to "speak up" about risk and make a commitment to act on the concerns voiced by their staff members and hold staff accountable for expected behaviors.

Adverse events occur in one out of seven patients.<sup>38</sup> The patient is considered the first victim in an event that did not go as intended. After a medical error occurs, the organization has a responsibility to both the patient and the healthcare personnel involved in the event. The patient wants an honest explanation and the facts about the occurrence. Additionally, they want an apology for the situation, to know the plan for fixing their problem, and some assurance that efforts are being made to prevent recurrence. In 2000, Dr. Albert Wu described healthcare personnel involved in an unanticipated adverse event as the second victim. These involved providers may feel personally responsible for the unexpected outcome and believe they failed the patient and may demonstrate doubts in clinical skills and knowledge base.<sup>39</sup> The healthcare personnel involved in a medical error want a system assessment, the support of colleagues, a sense of shared responsibility for the error (with leadership), a preventive action plan, a commitment to fix system problems, and often, psychological counseling.<sup>40</sup>

Reporting programs are generally designed to target problem areas through trend analysis, create an information base to assist in creation of corrective and prevention measures, spread knowledge about risk, and promote open communication. Until we know the scope of any problem and stratify risk and harm into categories, it is difficult to plan for improvement. Improved risk/event reporting should lead to higher quality patient care delivery. As with surveillance for HAIs, raising awareness and strengthening a safety culture will initially increase the detection of errors or incident rates, and it is important to educate leadership and staff to expect this from improved surveillance and reporting. Eventually, the success of

the patient safety program can be measured to some degree by increased reporting and decreased incidents that result in patient harm. Better reporting is only the first step. It is a challenge to engage clinicians and others who have demanding jobs and competing priorities in performance improvement and intervention efforts, but this is the key to improved clinical outcomes.

John Eisenberg, the first director of the AHRQ, outlined criteria for successful reporting systems when he opened the Fourth Decennial Conference on Nosocomial Infections by stating that the CDC's National Nosocomial Infection Surveillance (NNIS) program was an excellent model for patient safety programs. Eisenberg outlined reasons for the success of the NNIS reporting system: (1) it is voluntary and confidential; (2) it utilizes standardized definitions, numerators, denominators, and protocols; (3) it targets high-risk populations (ICU, surgical); (4) it demands that an adequate number of staff members are dedicated to data collection; (5) it provides a large sample size; (6) it disseminates data back to care providers; and (7) it monitors rates and links to prevention efforts.

Patient safety event or incident reporting systems also need to stratify data whenever possible. Systems should include a method for categorizing harm to patients, sometimes referred to as a "harm score." Harm scores can include broad categories such as: no error, error but no harm, error with harm, and error with death as outcome. The Medication Errors Reporting Program (MERP), operated by the United States Pharmacopeia (USP) in cooperation with the Institute for Safe Medication Practices (ISMP), is a confidential national voluntary reporting program that uses a harm score to categorize medication errors. MERP provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern. Without reporting, such events would go unrecognized, and thus important epidemiological and preventive information would be unavailable. Errors, near misses, or hazardous conditions may be reported to the program. These include, but are not limited to, administration of the wrong drug or the wrong strength or dose of medication; confusion over LASA drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications. Case studies are published by ISMP and/or USP to alert healthcare professionals and others about recommendations to prevent errors.

In addition to medication errors, educating employees about what to report should begin with the TJC list of sentinel events. As defined by the TJC, a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, "or the risk thereof." Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. TJC defines sentinel events and requires accredited facilities to complete a thorough and credible root-cause analysis and action plan within 45 calendar days of becoming aware of the event. In addition, voluntary reporting to TJC at the time of the event is strongly encouraged. Not all adverse events are considered sentinel events. Several safety organizations such as the National Quality Forum and Healthcare Performance Improvement (HPI) has endorsed a list of serious reportable events (SREs) and has set criteria to assist facilities in classifying serious safety events (SSEs). TJC sentinel events include:<sup>41</sup>

- Any unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition
- The event is one of the following (even if the outcome was not death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition):
  - Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge

- Unanticipated death of a full-term infant
- Abduction of any patient receiving care, treatment, and services
- Discharge of an infant to the wrong family
- Rape, assault (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment, and services
- Rapes, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare organization
- Invasive procedure, including surgery, on the wrong patient or other invasive procedure
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Severe neonatal hyperbilirubinemia (bilirubin > 30 mg/dL)
- Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25 percent above the planned radiotherapy dose
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities

While creating a culture of safety and convincing staff to increase reporting, there will be some myths or unspoken rules that need to change if decreasing medical error is the goal. These unspoken rules have developed over time because of the stigma attached to errors. Inadequate staffing, poor understanding of procedures and other constraints may inadvertently create normalized deviance, driving staff members to protect themselves and their colleagues by independently changing practice and creating nonstandard work when they feel it is in their patients' best interest. As a result, important information about the cause of errors is lost and system problems can become more difficult to address.

Risk identification and patient safety reporting programs can collect data using paper incident forms, online report entry, card-based information, and telephone hotlines. Reporting systems must be readily available and accessible by all members of the healthcare team, and they must be user-friendly and secure. The best reporting programs keep information confidential, which is often the greatest catalyst to improved safety event reporting.

Risk analysis of reported aggregate data must look at trends in type of errors, people, systems, and processes involved; place and time of occurrence; and risk factors identified. This information should be shared with key stakeholders and used to drive improvements that reduce risk of harm to patients (and employees).

## Interventions to Reduce Adverse Events in Healthcare

"Patients should not be harmed by the care that is intended to help them, nor should harm come to those who work in healthcare."<sup>1</sup>It is impossible to reduce medical errors and adverse outcomes by focusing in isolation on any one aspect of the healthcare system. Patient safety must be analyzed from the national level, where health policy and legislation are created, down to the frontline of patient care delivery. The second IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century*,<sup>42</sup>states that "all healthcare organizations should adopt as their explicit purpose to continually reduce the burden of illness, injury and disability, and to improve the health and functioning of the people of the United States." To close the quality chasm between what we know our consumers deserve and what the system is able to consistently deliver, the chasm report suggests that the healthcare system focus on six aims:



1. Patient safety, the fundamental cornerstone of the healthcare system: Care provided in a safe manner, in a safe environment, recognizing that humans will make mistakes and that errors do occur. The goal must be to prevent harm before it reaches the patient and affects the healthcare personnel adversely (the "second victim" of medical errors). Everyone is involved in seeking out risk and identifying opportunities to make care safer and learning from medical errors and near misses.
2. Patient-centeredness: We must focus on the patient's experience of illness and receiving healthcare and on systems that work or fail to work to meet individual patient's needs. Patient's values, preferences, and expressed needs should be at the center of decisions made. Coordination and integration of care, information, communication, education, physical comfort, emotional support, and involvement of family and friends must be factored into care plans and actions. Finally, every patient must have access to high-quality care.
3. Effectiveness: The IOM defines effectiveness as "care that is based on the use of systematically acquired evidence to determine whether an intervention produces better outcomes than alternatives—including the alternative of doing nothing." This premise is the foundation upon which evidence-based medicine rests. Effective care depends on the triad of: (1) the best research evidence from well-designed experiments, trials, and studies; (2) clinical expertise; and (3) the patient's values, preferences, concerns, and expectations.
4. Efficiency: The efficiency of the system can be improved through two primary methods: reducing quality waste and reducing administrative or production costs. Quality waste refers to the overuse of services (where a healthcare service is provided when the potential risks outweigh the benefits) and the elimination of medical errors. Administrative and production waste can be reduced by eliminating duplicative work processes (especially paperwork), redundant testing, and multiple reentries of various types of practitioner orders.
5. Equity: Simply stated, the benefits of the healthcare system should be available to everyone. All disparities in providing healthcare must be removed at the population and individual levels that are based on race, ethnicity, gender, or ability to pay.
6. Timeliness: At all levels of the organization, focus must be on ensuring that patient care processes flow smoothly. This means that long waits to access care, receive diagnostic testing and treatments, and obtain test results upon which to base decisions must be decreased or eliminated.

In healthcare organizations, surveillance, reporting, and analysis are the foundation of risk prevention programs, but targeted interventions must be deployed if patient safety programs are to be successful in reducing harm from medical errors and other adverse events. Several organizations have analyzed the effectiveness of guidelines, standards of care, and prevention measures in order to recommend evidence-based measures for improving patient safety. These include the AHRQ, NQF, CDC, National Patient Safety Foundation (NPSF), TJC, and CMS. Although not an exhaustive list, some of these measures are outlined here. (The CDC guidelines for the prevention of HAIs are not discussed here, although these are some of the best evidence-based and scientifically tested guidelines focused on prevention of adverse events.)

In 2002, the first attempt was made by regulatory and accreditation agencies to develop and publish national standards for healthcare institutions to adopt in order to improve the most common types of medical errors. Organizations accredited by TJC were expected to be fully compliant with the first set of National Patient Safety Goals (NPSGs) by January 2003. Each year, a multidisciplinary expert advisory board reviews current trends in medical errors and attempts to expand prevention efforts through updated versions of these patient safety goals.



In 2004, TJC included infection prevention and control processes within the NPSGs. Goal 7 was created to address healthcare personnel education and compliance with hand hygiene and the inclusion of healthcare-associated deaths and disability as sentinel events, requiring root cause analysis and follow-up. This NPSG was substantively expanded upon in 2009 to include patient education regarding multidrug-resistant organisms and patient and family engagement in patient safety related to HAIs. Additionally, this goal requires facility implementation of evidence-based practices to prevent device and procedure-associated infections.<sup>43</sup>

The NQF published *Safe Practices for Better Health Care* to highlight the evidence, or lack thereof, surrounding various patient safety interventions.<sup>44</sup> The NQF report outlines priority healthcare safe practices that should be implemented in all clinical settings to reduce the risk for harm. These "voluntary consensus standards" were selected from over 200 practices reviewed based on the practice's specificity, effectiveness, potential benefit, generalizability, and readiness for implementation. The practices are organized into categories:

- Creating a culture of safety
- Matching healthcare needs with service delivery capability
- Facilitating information transfer and clear communication
- Increasing safe medication use

Implementation of the recommended practices at healthcare facilities will depend on the organization's own priorities and circumstances, such as availability of resources, practices already implemented, environmental constraints, and patient mix/population needs. The report also recommends specific actions related to dissemination and implementation of the safe practices, measuring their implementation, and updating and improving the set of practices. The current safe practices are detailed in Table 18-2.

The patient safety literature citing evidence-based prevention measures credits the field of hospital epidemiology and infection prevention with successful interventions to reduce risk and adverse outcomes. AHRQ recommends that all healthcare organizations focus on the following infection prevention initiatives:

- Improving hand hygiene
- Utilizing barrier precautions to prevent transmission of infection
- Prudent antibiotic use to reduce *Clostridium difficile* and vancomycin-resistant enterococcus (VRE)
- Preventing urinary tract infections
- Preventing central venous catheter (CVC)-related bloodstream infections (BSIs)
- Preventing ventilator-associated pneumonia (VAP)
- Preventing surgical site infections (SSIs)

## **Serious Adverse and Sentinel Event Investigation: Root Cause Analysis and Failure Mode and Effects Analysis**

Following a serious adverse or sentinel event, whether resulting in harm or not, an intensive investigation should occur. Root cause analysis (RCA) is a process for identifying the basic or causal factors that underlie variation in performance. RCA is done if, after a fact-gathering debriefing with the team involved in the critical event, a determination is made that the event meets the definition of a

sentinel event or serious safety event. Timely communication and making sure a patient is protected from substandard or remedial measures is paramount.

When TJC added to the NPSGs a requirement that healthcare organizations manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with an HAI, this goal compels us to create a system for identifying possible HAI-related deaths. Methods may include working with health information management (medical records) personnel to identify all deaths, comparing hospital deaths with HAI database to identify potential HAI-related deaths, and working with the hospital epidemiologist or infection prevention and control committee chair to review records to determine if death or disability was "unanticipated." Knowing expected mortality rates associated with each type of HAI is critical for managing this work. Though difficult, it will be important to determine whether all evidence-based practices were applied to a case to determine if the HAI may have been preventable.

In most organizations, experts in risk management or performance improvement departments are responsible for facilitating the RCA process and can assist IPs, content experts, with an intense investigation. Administrative leaders are instrumental in supporting change that occurs at the sharp-end of healthcare and can ensure interdisciplinary involvement in action plan completion. The steps in conducting RCA are similar to those used to do outbreak investigations or even plan-do-check-act (PDCA). The TJC created a framework, Table 18-3, to use to ensure that all elements of RCA are addressed.<sup>45</sup>

Carrico and Ramirez proposed a process for evaluating death due to infection as part of the sentinel event analysis process. Their method provides an algorithm to assist the IP with making critical determinations in the evaluation process and helps guide documentation and formation of multidisciplinary teams to identify potential gaps in ideal processes.<sup>46</sup>For additional reference, the Association for Professionals in Infection Control and Epidemiology (APIC) designed an infection prevention-specific framework to support the investigation an infection-related sentinel event<sup>47</sup>available at: [http://www.apic.org/Resource\\_/TinyMceFileManager/Position\\_Statements/Sentinel-Event.pdf](http://www.apic.org/Resource_/TinyMceFileManager/Position_Statements/Sentinel-Event.pdf).

Part of the serious adverse and sentinel event investigation process may include conducting a Failure Modes and Effects Analysis (FMEA). FMEA is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.<sup>48</sup>

Teams use FMEA to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred. This emphasis on prevention may reduce risk of harm to both patients and staff. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.<sup>49</sup>The greatest strength of failure mode and effects analysis lies in its ability to focus users on the process of redesigning potentially problematic processes to prevent the occurrence of failures.

If a particular failure cannot be reliably prevented, FMEA then focuses on protections that could be implemented to prevent the failure from reaching the patient, or, in the worst case, mitigate its effects if it reaches the patient. The major components are outlined here:<sup>49</sup>

- **Failure (F):** Lack of success, nonperformance, nonoccurrence, or breaking down or ceasing to function. It takes place when a system or part of a system performs in a way that is not intended or desirable.
- **Mode (M):** The way of operating or using a system or process, or a way or manner in which a thing is done. A mode is the way or manner in which something, such as a failure, can happen. Combining the words failure and mode, a *failure mode* is the manner by which something can fail. A failure mode generally describes the way the failure occurs and its impact on a process. Any step in a process can fail, and each failure may have many failure modes.
- **Effects (E):** The results or consequences of an action. Effects are the results of failure modes. They might be direct or indirect, long- or short-term, or likely or unlikely. In any case, they are the result of the impact of a particular failure mode on the stability of the entire process or a portion thereof. A failure effect is the consequence(s) a failure mode has on the operation, function, or status of a process step. In healthcare, effects generally are classified according to the outcome of the process—the impact on the care recipient.
- **Analysis (A):** The detailed examination of the elements or structure of something, perhaps a process, substance, or situation. An FMEA team performs an analysis to determine possible failure modes and effects, how serious the possible effects could be, and ways to eliminate or reduce failure risk and prevent harm.

**Table 18-2.** The National Quality Forum Endorsed Set of Safe Practices<sup>44</sup>

**Table 18-2** The National Quality Forum Endorsed Set of Safe Practices

SAFE PRACTICE	PRACTICE STATEMENT
Safe Practice 1: Leadership Structures and Systems	Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.
Safe Practice 2: Culture Measurement, Feedback, and Intervention	Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk.
Safe Practice 3: Teamwork Training and Skill Building	Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients.
Safe Practice 4: Identification and Mitigation of Risks and Hazards	Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.
Safe Practice 5: Informed Consent	Ask each patient or legal surrogate to "teach back," in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.
Safe Practice 6: Life-Sustaining Treatment	Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart.
Safe Practice 7: Disclosure	Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.

Safe Practice 8: Care of the Caregiver	Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events.
Safe Practice 9: Nursing Workforce	<p>Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following:</p> <ul style="list-style-type: none"> <li>• A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety.</li> <li>• Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team.</li> <li>• Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services.</li> <li>• Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills.</li> </ul>
Safe Practice 10: Direct Caregivers	Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.
Safe Practice 11: Intensive Care Unit Care	All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified").
Safe Practice 12: Patient Care Information	Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and to all of the patient's healthcare providers/ professionals, within and between care settings, who need that information to provide continued care.
Safe Practice 13: Order Read-Back and Abbreviations	<p>Incorporate within the organization a safe, effective communication strategy, structures, and systems to include the following:</p> <ul style="list-style-type: none"> <li>• For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and "read-back" the complete order or test result.</li> <li>• Standardize a list of "Do Not Use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.</li> </ul>
Safe Practice 14: Labeling of Diagnostic Studies	Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time.
Safe Practice 15: Discharge Systems	A "discharge plan" must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for postdischarge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge.
Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry	Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure.
Safe Practice 17: Medication Reconciliation	The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care.
Safe Practice 18: Pharmacist Leadership Structures and Systems	Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.

Safe Practice 19: Hand Hygiene	Comply with current Centers for Disease Control and Prevention (CDC) Hand Hygiene Guidelines.
Safe Practice 20: Influenza Prevention	Comply with current CDC recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control.
Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention	Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices.
Safe Practice 22: Surgical-Site Infection Prevention	Take actions to prevent surgical-site infections by implementing evidence-based intervention practices.
Safe Practice 23: Care of the Ventilated Patient	Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers.
Safe Practice 24: Multidrug-Resistant Organism Prevention	Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections. Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant <i>Staphylococcus aureus</i> , vancomycin-resistant enterococci, and <i>Clostridium difficile</i> . Multidrug-resistant gram-negative bacilli, such as <i>Enterobacter</i> species, <i>Klebsiella</i> species, <i>Pseudomonas</i> species, and <i>Escherichia coli</i> , and vancomycin-resistant <i>Staphylococcus aureus</i> , should be evaluated for inclusion on a local system level based on organizational risk assessments.
Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention	Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices.
Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention	Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery for all invasive procedures.
Safe Practice 27: Pressure Ulcer Prevention	Take actions to prevent pressure ulcers by implementing evidence-based intervention practices.
Safe Practice 28: Venous Thromboembolism Prevention	Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.
Safe Practice 29: Anticoagulation Therapy	Organizations should implement practices to prevent patient harm due to anticoagulant therapy.
Safe Practice 30: Contrast Media-Induced Renal Failure Prevention	Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations.

Safe Practice 31: Organ Donation	Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process.
Safe Practice 32: Glycemic Control	Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.
Safe Practice 33: Falls Prevention	Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.
Safe Practice 34: Pediatric Imaging	When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation.

Table 18-3.TJC Root Cause Analysis and Action Plan Framework Template45

When did the event occur?

Table 18-3

Date:	Day of the week:	Time:
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Detailed Event Description Including Timeline:

Table 18-4

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Diagnosis:

Table 18-4

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Medications:

Table 18-4

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Autopsy Results:

Table 18-5

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Past Medical/Psychiatric History:

Table 18-4

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Table 18-6 Analysis, Prompts, Root Causes

#	Analysis Question	Prompts	Root Cause Analysis Findings	Root Cause	Plan of Action

1	What was the intended process flow?	<p>List the relevant process steps as defined by the policy, procedure, protocol, or guidelines in effect at the time of the event. You may need to include multiple processes.</p> <p><b>Note:</b>The process steps <i>as they occurred in the event</i> will be entered in the next question.</p> <p>Examples of defined process steps may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Site verification protocol</li> <li>• Instrument, sponge, sharps count procedures</li> <li>• Patient identification protocol</li> <li>• Assessment (pain, suicide risk, physical, and psychological) procedures</li> <li>• Fall risk/fall prevention guidelines</li> </ul>
2	Were there any steps in the process that did not occur as intended?	<p>Explain in detail any deviation from the intended processes listed in Analysis Item #1 above.</p>
3	What human factors were relevant to the outcome?	<p>Discuss staff-related human performance factors that contributed to the event.</p> <p>Examples may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Boredom</li> <li>• Failure to follow established policies/procedures</li> <li>• Fatigue</li> <li>• Inability to focus on task</li> <li>• Inattentional blindness/confirmation bias</li> <li>• Personal problems</li> <li>• Lack of complex critical thinking skills</li> <li>• Rushing to complete task</li> <li>• Substance abuse</li> <li>• Trust</li> </ul>
4	How did the equipment performance affect the outcome?	<p>Consider all medical equipment and devices used in the course of patient care, including AED devices, crash carts, suction, oxygen, instruments, monitors, infusion equipment, etc. When discussing, provide information on the following, as applicable:</p> <ul style="list-style-type: none"> <li>• Descriptions of biomedical checks</li> <li>• Availability and condition of equipment</li> <li>• Descriptions of equipment with multiple or removable pieces</li> <li>• Location of equipment and its accessibility to staff and patients</li> <li>• Staff knowledge of or education on equipment, including applicable competencies</li> <li>• Correct calibration, setting, operation of alarms, displays, and controls</li> </ul>



5	What controllable environmental factors directly affected this outcome?	<p>What environmental factors within the organization's control affected the outcome?</p> <p>Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Overhead paging that cannot be heard</li> <li>• Safety or security risks</li> <li>• Risks involving activities of visitors</li> <li>• Lighting or space issues</li> </ul> <p>The response to this question may be addressed more globally in Question #17. This response should be specific to this event.</p>
6	What uncontrollable external factors influenced this outcome?	Identify any factors the organization cannot change that contributed to a breakdown in the internal process, for example natural disasters.
7	Were there any other factors that directly influenced this outcome?	List any other factors not yet discussed.
8	What are the other areas in the organization where this could happen?	<p>List all other areas in which the potential exists for similar circumstances. For example:</p> <ul style="list-style-type: none"> <li>• Inpatient surgery/outpatient surgery</li> <li>• Inpatient psychiatric care/outpatient psychiatric care</li> </ul> <p>Identification of other areas within the organization that have the potential to impact patient safety in a similar manner. This information will help drive the scope of the action plan.</p>
9	Was the staff properly qualified and currently competent for their responsibilities at the time of the event?	<p>Include information on the following for all staff and providers involved in the event. Comment on the processes in place to ensure staff is competent and qualified. Examples may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Orientation/training</li> <li>• Competency assessment (What competencies do the staff have and how do you evaluate them?)</li> <li>• Provider and/or staff scope of practice concerns</li> <li>• Whether the provider was credentialed and privileged for the care and services he or she rendered</li> <li>• The credentialing and privileging policy and procedures</li> <li>• Provider and/or staff performance issues</li> </ul>
10	How did actual staffing compare with ideal levels?	Include ideal staffing ratios and actual staffing ratios along with unit census at the time of the event. Note any unusual circumstance that occurred at this time. What process is used to determine the care area's staffing ratio, experience level, and skill mix?

11	What is the plan for dealing with staffing contingencies?	<p>Include information on what the organization does during a staffing crisis, such as call-ins, bad weather, or increased patient acuity.</p> <p>Describe the organization's use of alternative staffing. Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Agency nurses</li> <li>• Cross training</li> <li>• Float pool</li> <li>• Mandatory overtime</li> <li>• PRN pool</li> </ul>
12	Were such contingencies a factor in this event?	If alternative staff were used, describe their orientation to the area, verification of competency, and environmental familiarity.
13	Did staff performance during the event meet expectations?	Describe whether staff performed as expected within or outside of the processes. To what extent was leadership aware of any performance deviations at the time? What proactive surveillance processes are in place for leadership to identify deviations from expected processes? Include omissions in critical thinking and/or performance variance(s) from defined policy, procedure, protocol, and guidelines in effect at the time.
14	To what degree was all the necessary information available when needed? Accurate? Complete? Unambiguous?	<p>Discuss whether patient assessments were completed, shared, and accessed by members of the treatment team, to include providers, according to the organizational processes.</p> <p>Identify the information systems used during patient care.</p> <p>Discuss to what extent the available patient information (e.g., radiology studies, lab results, or medical record) was clear and sufficient to provide an adequate summary of the patient's condition, treatment, and response to treatment.</p> <p>Describe staff utilization and adequacy of policy, procedure, protocol, and guidelines specific to the patient care provided.</p>
15	To what degree was the communication among participants adequate for this situation?	<p>Analysis of factors related to communication should include evaluation of verbal, written, electronic communication or the lack thereof. Consider the following in your response, as appropriate:</p> <ul style="list-style-type: none"> <li>• The timing of communication of key information</li> <li>• Misunderstandings related to language/cultural barriers, abbreviations, terminology, etc.</li> <li>• Proper completion of internal and external hand-off communication</li> <li>• Involvement of patient, family, and/or significant other</li> </ul>

16	<p>Was this the appropriate physical environment for the processes being carried out for this situation?</p> <p>Consider processes that proactively manage the patient care environment. This response may correlate to the response in question 6 on a more global scale.</p> <p>What evaluation tool or method is in place to evaluate process needs and mitigate physical and patient care environmental risks?</p> <p>How are these process needs addressed organization-wide?</p> <p>Examples may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Alarm audibility testing</li> <li>• Evaluation of egress points</li> <li>• Patient acuity level and setting of care managed across the continuum</li> <li>• Preparation of medication outside of pharmacy</li> </ul>
17	<p>What systems are in place to identify environmental risks?</p> <p>Identify environmental risk assessments.</p> <ul style="list-style-type: none"> <li>• Does the current environment meet codes, specifications, regulations?</li> <li>• Does staff know how to report environmental risks?</li> <li>• Was there an environmental risk involved in the event that was not previously identified?</li> </ul>
18	<p>What emergency and failure- mode responses have been planned and tested?</p> <p>Describe variances in expected process due to an actual emergency or failure mode response in connection to the event.</p> <p>Related to this event, what safety evaluations and drills have been conducted and at what frequency (e.g., mock code blue, rapid response, behavioral emergencies, patient abduction, or patient elopement)?</p> <p>Emergency responses may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Fire</li> <li>• External disaster</li> <li>• Mass casualty</li> <li>• Medical emergency</li> </ul> <p>Failure mode responses may include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Computer down time</li> <li>• Diversion planning</li> <li>• Facility construction</li> <li>• Power loss</li> <li>• Utility issues</li> </ul>
19	<p>How does the organization's culture support risk reduction?</p> <p>How does the overall culture encourage change, suggestions, and warnings from staff regarding risky situations or problematic areas?</p> <ul style="list-style-type: none"> <li>• How does leadership demonstrate the organization's culture and safety values?</li> <li>• How does the organization measure culture and safety?</li> <li>• How does leadership establish methods to identify areas of risk or access employee suggestions for change?</li> <li>• How are changes implemented?</li> </ul>

20	What are the barriers to communication of potential risk factors?	Describe specific barriers to effective communication among caregivers that have been identified by the organization. For example, residual intimidation or reluctance to report coworker activity.  Identify the measures being taken to break down barriers (e.g., use of SBAR). If there are no barriers to communication, discuss how this is known.
21	How is the prevention of adverse outcomes communicated as a high priority?	Describe the organization's adverse outcome procedures and how leadership plays a role within those procedures.
22	How can orientation and in-service training be revised to reduce the risk of such events in the future?	Describe how orientation and ongoing education needs of the staff are evaluated and discuss its relevance to event. (e.g., competencies, critical thinking skills, use of simulation labs, evidence-based practice, etc.).
23	Was available technology used as intended?	Examples may include but are not limited to: <ul style="list-style-type: none"> <li>• CT scanning equipment</li> <li>• Electronic charting</li> <li>• Medication delivery system</li> <li>• Tele-radiology services</li> </ul>
24	How might technology be introduced or redesigned to reduce risk in the future?	Describe any future plans for implementation or redesign. Describe the ideal technology system that can help mitigate potential adverse events in the future.

FMEA can be used to improve many types of processes or subprocesses. High-risk patient care processes provide the natural starting place. High-risk processes are those in which a failure of some type will most likely jeopardize the safety of the individuals served by the healthcare organization. Processes that will benefit from FMEA may be new to the organization or they may be existing and potentially (or actually) problematic. A subprocess may be singled out for an FMEA, or the analysis might cover the entire process. FMEA can be used proactively either before a new process is put in place or before a process that has been redesigned "goes live" following a root cause analysis due to a sentinel event.<sup>49</sup>

In summary, FMEA can improve the safety of individuals receiving care by preventing failures and preventing injury and harm from near misses when, despite an organization's best efforts, failures do occur. FMEA can narrow or eliminate gaps in quality and performance and yield improved outcomes.

## The Role of the Infection Preventionist in Patient Safety

Most people associate going to a hospital with being in a clean, often sterile environment, and do not expect infection to be a possible outcome of hospitalization. The reality is that HAIs are the fourth leading cause of death in the United States, after heart disease, cancer, and stroke. Most people can imagine the devastation of an infection, even those who have not read the Harvard Medical Practice

Study, which pointed to SSIs as the number two adverse event experienced by hospitalized patients.<sup>5</sup>

The statistics in the literature are largely made of up infections that occur in hospitals, accounting for only part of the problem. IPs track infectious adverse events in and outside of the traditional healthcare environment—in long-term care, home health, and outpatient surgery and dialysis units. Few clinicians have the widespread, comprehensive view of adverse events that IPs bring to the patient safety arena.

Surveillance, prevention, and control measures are the foundation of any program whose aim is to identify and categorize risk, using problem-solving techniques and critical thinking skills to eliminate injury and harm. These fundamental skills and core competencies are what IPs bring to patient safety programs. Marketing these skills and competencies is how IPs can demonstrate their value to healthcare leaders interested in improving the safety and quality of clinical care. Volunteering to participate in and, if possible, lead an organization's patient safety efforts may include: active membership on the patient safety committee, offering training and courses in the principles of epidemiology, assisting with the set up or evaluation of surveillance programs for medication errors or falls, or guiding a team through the process of developing interventions to reduce the incidence of SSIs. The education of healthcare personnel is a fundamental intervention to prevent HAI. A systematic review to determine the effect of educational strategies of healthcare personnel for reducing HAIs was conducted and demonstrated that educational interventions may reduce HAIs considerably.<sup>50</sup> The IP can be an important effector for this education strategy.

APIC and the Infection Prevention and Control Canada (IPAC) professional practice standards<sup>51</sup> outline the skills and competencies that IPs need in order to be effective managers and leaders in hospital epidemiology and infection prevention and control programs. More recently APIC published a competency model that acknowledged professional attributes such as teamwork, reasoning, values, and communication as equivalent to traditional skills of knowledge and technical proficiency.<sup>52</sup> These practice and behavioral standards should be part of the position description and performance appraisal of every IP, since they demonstrate the valuable assets brought to the organization's patient safety program.

The most valuable asset IPs bring to organizational patient safety efforts is a practice based on the science of epidemiology: the study of populations, characterized by time, place, and risk factors; use of proper definitions and measurements; and use of appropriate study designs.

Epidemiologic skills used to reduce endemic infection rates through surveillance and prevention activities can be applied to the study of any adverse outcome of healthcare. Once indicators are selected to measure adverse outcomes, the same competencies are needed:

- Data management: collection, organization, analysis, reporting
- Feedback of data and information to key stakeholders
- Education of healthcare personnel about risks and reduction strategies
- Development and implementation of interventions to reduce risk and improve processes
- Evaluation of interventions based on data (improved rates or processes)
- Continued surveillance and prevention activities

The role of the IP has historically been and will continue to be critical to ensuring patient safety through the establishment of evidence-based infection prevention practices and ensuring their full deployment through education, audit, and performance improvement. The federal agency emphasis, regulatory body

requirement, and the public's demand for attention to HAIs ensure the valuable role of the IP in patient safety reform.

## Conclusions

Active participation of IPs is a key element of success within any healthcare organization's patient safety program. The IP can facilitate the integration of evidence-based research into practice and can direct the priorities of the organization's patient safety plan. The IP must stay focused, despite many competing priorities, on developing and facilitating the standard implementation of evidence-based interventions to reduce HAIs. Root-cause analyses and the development of performance improvement action plans are an expectation of the IP role. IPs are the organization's internal infection prevention, control patient safety expert, and must remain closely aligned with initiatives to reduce any and all adverse outcomes of healthcare.

The publication and enforcement of the NPSGs has helped to elevate the importance of hospital epidemiology, infection prevention and control programs, and the IP. The critical role of hand hygiene in the prevention of HAIs has now become an enforceable safety standard. IPs have shared data and information about the positive effects of hand hygiene for years. Now we are challenged to creatively use limited resources to observe, measure, and improve compliance. The IPs' professional responsibilities will continue to evolve. Becoming familiar with patient safety language will help facilitate interventions as IPs partner with a variety of disciplines and colleagues on designing safe, reliable systems to support infection prevention. Building on the science of infection prevention and control will assist IPs in developing reformative and sustainable changes in our healthcare industry.

## Future Trends

Public reporting of outcomes and the linking of reimbursement to these outcomes will continue to challenge healthcare organizations. Organizations must learn to tolerate and balance the competing efforts to improve medical record coding of "present on admission" in order to recognize that some organizations that scan for more deep vein thromboses (DVTs) may indeed diagnose more DVTs within the overall effort to reduce the prevalence of these adverse events. The engagement of the patient and family as critical and active partners in ensuring adherence to evidence-based processes will be an important complement to existing efforts. "Have you cleaned your hands?" "Can you explain this consent form to me in a more understandable manner?" "What medications are you giving to me today and have you checked my allergies?" These are all simple yet very powerful patient safety interventions in which patients and family members can participate. Healthcare must welcome its most effective, although until now somewhat silent partners, in ensuring safe patient care.

## International Perspective

Improving patient safety is a global issue with a global impact. This has been evidenced through outbreak investigations involving pharmaceuticals and single-use and reprocessed medical supplies. In addition, the safety issues involving multidrug-resistant organisms and emerging infections that affect multiple countries continue to be a large part of safety initiatives. Patient safety initiatives will continue to be part of both strong and weak relationships among healthcare providers worldwide.

## Supplemental Resources

Agency for Healthcare Research and Quality (AHRQ). Available at: [www.ahrq.gov](http://www.ahrq.gov)

American Hospital Association (AHA). Available at: [www.hospitalconnect.com](http://www.hospitalconnect.com)

American Society for Healthcare Risk Management (ASHRM). Available at: <http://www.ashrm.org/>

Association of Health Care Pharmacists (AHCP). Available at: [www.ashp.org](http://www.ashp.org)

Association of Operating Room Nurses (AORN). Available at: [www.aorn.org](http://www.aorn.org)

Association for Professionals in Infection Control and Epidemiology (APIC). Available at: [www.apic.org](http://www.apic.org)

Centers for Disease Control and Prevention (CDC). Available at: [www.cdc.gov](http://www.cdc.gov)

Institute for Healthcare Improvement (IHI). Available at: [www.ihl.org/](http://www.ihl.org/)

Institute for Safe Medication Practices (ISMP). Available at: [www.ismp.org](http://www.ismp.org)

The Joint Commission (TJC). Available at: [www.jointcommission.org/](http://www.jointcommission.org/)

Society for Healthcare Epidemiology of America (SHEA). Available at: [www.shea-online.org](http://www.shea-online.org)

Premier Safety Institute (PSI). Available at: [www.premierinc.com](http://www.premierinc.com)

QualityHealthcare.org. Available at: [www.qualityhealthcare.org](http://www.qualityhealthcare.org)

National Patient Safety Foundation (NPSF). Available at: [www.npsf.org](http://www.npsf.org)

National Quality Forum (NQF). Available at: [www.qualityforum.org](http://www.qualityforum.org)

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## Feedback form

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## Qualitative Research Methods

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### Abstract

*Historically, anthropologists and social scientists have used qualitative methods as a legitimate form of inquiry and research. More recently, other disciplines have used qualitative methods to complement and enhance the research methods used in the specific discipline. Qualitative research frequently uses an inductive approach in which the researcher moves from the event or process (the phenomenon observed) to the development of theory or structure. Inductive studies are generally exploratory, descriptive, and context specific. When more is known about the phenomenon of interest, a combination of qualitative and quantitative methods often is used. The development of knowledge about a research topic may involve moving in an iterative manner, back and forth between qualitative and quantitative research methods, for the purposes of identifying new insights and developing and testing hypotheses.*

### Key Concepts

- Qualitative research frequently uses an inductive approach in which the researcher moves from the event or process (the phenomenon observed) to the development of theory or structure.
- Inductive studies are generally exploratory, descriptive, and context specific.
- Deductive studies involve testing theory in which a research hypothesis is either rejected or accepted. In deductive studies, the researcher moves from the structure (the theory or hypothesis) to the event or process (phenomenon).
- The researcher needs to determine which research methodology, or combination of methodologies, will provide needed information about a research question. Exploratory research questions are likely to use qualitative design. In experimental research, when more is known about the specific variables and their relationships, a combination of qualitative and quantitative methods is often used.

- Qualitative research methods can be used to study phenomena of interest to infection preventionists, including healthcare personnel adherence to infection prevention recommendations (e.g., immunization schedules, hand hygiene, and safe surgical techniques).

## Background

During the 19th and early 20th centuries, anthropologists and other social scientists began to use qualitative research methods. As field investigations resulted in acceptable qualitative techniques for anthropologic research, qualitative methods became recognized as a legitimate form of research for social science disciplines. Sociologists used qualitative research methods in the early part of this century to study juvenile delinquency, immigrants, and minority groups. Although disciplines using the methods of qualitative research were varied, the methods themselves were, and continue to be, similar.<sup>1</sup>

Qualitative research methods are used to pursue knowledge that will provide new insights, result in reformulation of existing theory, or discover meanings. Qualitative research frequently uses an *inductive* approach in which the researcher moves from the event or process (the phenomenon observed) to the development of theory or structure. Inductive studies are generally exploratory, descriptive, and context specific, whereas *deductive* studies involve testing theory in which a research hypothesis is either rejected or accepted. In deductive studies, the researcher moves from the structure (the theory or hypothesis) to the event or process (phenomenon).

The research question determines the choice of research methods. Exploratory research questions often lend themselves to qualitative design. Generally, little is known about the phenomenon; the focus of the research is to identify variables, to describe a phenomenon within a real-world context (place and time), or to generate theory. When more is known about the phenomenon of interest, a combination of qualitative and quantitative methods is often used. Qualitative methods allow the researcher to dig deeper into phenomena that may be very well studied quantitatively but need to be understood in context. The researcher needs to determine which research methodology, or combination of methodologies, will provide needed information about a research question.

Qualitative methods are useful in studying an aspect of a quantitative question that needs deeper and richer exploration. The development of knowledge about a research topic may involve moving in an iterative manner back and forth between qualitative and quantitative research methods for the purposes of identifying new insights, developing hypotheses, establishing relationships, and testing hypotheses. In this manner, knowledge about a topic can be more fully explored and understood. This allows qualitative research methods to be used with quantitative methods to explain and further develop quantitative findings.<sup>2</sup>

Qualitative research methods can be used to study phenomena of interest to infection preventionists (IPs), including healthcare personnel (HCP) adherence to infection prevention recommendations (e.g., immunization schedules, hand hygiene, and safe surgical techniques). By using qualitative methods, IPs can systematically identify variables and relationships among variables that influence the practices and behavior of HCP. For example, information about hand hygiene behavior can be obtained from HCP regarding situations in which adherence is more likely to occur, patient situations with multiple obstacles to adherence to hand hygiene, and HCP perception of the consequences of noncompliance. Many IPs and quality improvement personnel in hospitals and other industries are currently using qualitative methods that facilitate the identification of HCP or client attitudes, beliefs, intentions, and social group norms that influence behavior and, ultimately, process and outcome.

# Basic Principles

## Introduction

In the Western world, quantitative research methods have been the dominant paradigm for studying health or healthcare issues. Natural science is associated with the study of observable, measurable phenomena, such as items of nature and natural events. An underlying belief of this approach is that objective facts can be studied in a neutral manner by unbiased researchers. The emphasis on quantitative research methods in healthcare is probably related to the natural science foundation of health sciences. *Positivism* is another term used to describe this approach to scientific knowledge that uses observation and verification by experiment.<sup>1,3,4</sup> Positivism focuses on finding truth through the physical, observable world. Quantitative research methods are consistent with the positivist approach because data are produced that can be counted or ordered in some way on a numeric scale.

Quantitative research may involve qualities that are not numeric but that can be assigned a numeric value. By counting or assigning numeric values to components of the item under study, the process is standardized.<sup>5</sup> Purposes of the positivist, natural science approach are generalization and prediction. An important criterion in quantitative research is the development or selection of research tools that will accurately measure the phenomenon under study. This criterion requires a considerable amount of knowledge about the phenomenon under study, before beginning research.

## Characteristics of Qualitative Research Designs

Qualitative study is characterized by its holistic and contextual nature.<sup>6</sup> Questions are explored through identification of patterns in narratives, observations, comparisons and contrasts, inferences, application of insight, and use of intuition.<sup>7</sup> Qualitative research can be exploratory, descriptive, or used for theory verification. In most qualitative studies, persons are not studied independently of their environment; rather, information is sought that will reflect present and past situations, and the emphasis is on the whole rather than on a part of an experience.<sup>8</sup> Detailed, in-depth descriptions of people and their experiences, as well as events and situations, are typical of qualitative data. The researcher may identify patterns or commonalities within data that will facilitate insights into underlying concepts. Often, researchers collect data that, as a result of new understandings, will lead to the generation of a hypothesis. Exploratory research using qualitative research is inductive. In contrast with the data collection tools of quantitative research, the data collection methods of qualitative research may be relatively unstructured, focusing on individual descriptions and observations.<sup>5</sup>

## Purposes

According to Patton,<sup>3</sup> the purposes of research are to:

- Contribute to basic knowledge and theory (basic research);
- Understand a problem so as to produce change (applied research);
- Improve a program (formative research); or
- Determine the effectiveness of a program (summative research).

Qualitative research may be used for any of these purposes:<sup>9</sup>



- Gain information when little is known about a topic;
- Develop understanding of how people perceive a phenomenon;
- More fully capture the human experience associated with an event;
- Identify the influence of cultural roles and norms on behavior;
- Identify variables and relationships among variables;
- Derive theories or hypotheses that can be used for future research;
- Generate theories or hypotheses that provide more complete insight into the phenomenon under study;
- Obtain additional information when what is known about a phenomenon seems incongruent with other information or appears to be biased, inconsistent, or outmoded; and
- Confirm theories.

## Qualitative Methods

### Types of Qualitative Research

The most common qualitative methods are phenomenology, grounded theory, and ethnography; the two approaches that are described in this chapter are ethnography and grounded theory.

#### *ETHNOGRAPHY*

Ethnographic research is guided by an intense desire to understand the lives of individuals and the meanings in human behavior.<sup>10</sup> The ethnographer aims to get at the nature of everyday experience within the context of culture. Participant observation, interviews, field notes, and archival data are used to provide in-depth description of everyday experience. Ethnographic methods involve collecting, describing, and analyzing data in a way that reflects the culture or subculture of people. Widely used in anthropology and sociology, and more recently in healthcare, ethnography provides understanding about how people interpret experiences, categorize events, and behave in a manner that reflects their cultural experience. Each cultural system provides a way of interpreting and classifying phenomena and generating behavior. Ethnography is grounded in cultural theory and provides understanding by obtaining the participant's perceptions within a specific context of time and place. In ethnography, the researcher uses language and terms specific to a culture to find common cultural patterns occurring within the studied population.<sup>11</sup>

For example, a study of the language and terms used to describe acquired immunodeficiency syndrome (AIDS) in Haiti provided the researcher with insight into not only the influence of political events on AIDS but also the cultural explanations regarding the cause and treatment of AIDS.<sup>12</sup> For example, AIDS could occur naturally from sexual contact with someone who is infected or through sorcery in which the infection is "sent" by someone who willfully wishes to inflict death on another.<sup>12</sup> Likewise, a study of villagers in northern Thailand regarding their perceptions of risks related to AIDS found that the AIDS information that was presented was too abstract and, in the judgment of the villagers, not pertinent to the local community.<sup>13</sup> Personal perceptions of risk were influenced by the meanings attached to the disease by the local community, not by AIDS information from sources distant from the village.<sup>13</sup>

Another example of the use of ethnographic methods to understand factors influencing acceptance of health-enhancing practices was reported by Wellin,<sup>14</sup> in which a health education campaign to persuade villagers in Peru to boil drinking water failed. In this report, the lack of recognition of the importance of interpersonal networks was critical to the failure of the water boiling campaign. If ethnographic methods had been used to evaluate this project, the researcher may have discovered other, less obvious reasons for poor project results. By taking the time to ask questions and listen intensely, the researcher could better understand how to develop interventions targeted to specific beliefs; attitudes; and social, cultural, and environmental factors.

### *Grounded Theory*

Grounded theory attempts to identify underlying themes surrounding a particular social or psychological process to formulate theory.<sup>15</sup> The term *grounded* is used because the theories that emerge are grounded in the data.<sup>5</sup> In this qualitative research method, data are studied, coded, and compared until themes emerge. By reducing the data into themes that are compared and contrasted with one another, relationships between themes emerge and are used to develop hypotheses and generate theory.<sup>5,15,16</sup> The purpose of grounded theory is not to provide proof for an existing theory but to collect and analyze data in a manner that allows theory to emerge directly from the data.

A grounded theory approach was used to examine the function and roles of nurses in the care of peripheral venous cannulae (PVCs).<sup>17</sup> Participants were medical or surgical nurses in an Irish national specialty hospital. The nurses were interviewed about their understanding of nurses' activities related to duration of PVCs, complications, and prevention measures. By using the methods of grounded theory, the coping strategies of Canadian nurses who cared for patients with AIDS were identified, and researchers found that creating and maintaining a sense of control allowed these nurses to cope with the stresses of uncertainty in providing care to patients with AIDS.<sup>18</sup>

## Conducting Qualitative Research

The research question will drive the choice of qualitative method. In turn, the choice of the qualitative method determines the type of data collected and the data analysis method used. To understand the phenomenon under study, the researcher approaches the problem by gathering data. By using an inductive approach, the researcher does not begin with assumptions about the strength of the relationships between and among the variables. During analysis, patterns or commonalities that are present in the phenomenon under study emerge.<sup>3</sup>

### *Sample Selection*

In qualitative research, the sampling is generally purposive. Respondents are selected for the insights they may provide to the phenomenon under study. In contrast with quantitative research, respondents are not selected in a stratified, randomized process so that the findings can be generalized to the population; respondents are deliberately selected for the likelihood that they will possess information about the research topic. For example, when collecting information about the use of protective devices in surgery, the researcher may choose to interview only those surgeons who practice in the specialties that are reported to be at increased risk for exposure to patients' blood. Purposive strategies often use "linkage" sampling techniques, which are based on and reflect relationships that exist within the group. Snowballing is a common linkage technique in which initially selected individuals are asked to refer

others to the study.<sup>1,19</sup> Data gathering continues within reasonable limits until data saturation is reached (i.e., no new information is obtained or no new insights emerge).<sup>1</sup>

Focus groups were conducted with a sample of nurses purposefully selected from patient care units expected to provide care to victims of a bioterrorism event.<sup>20</sup> By using a grounded theory method, additional focus groups were conducted until no new concepts were identified by participants. The beliefs, fears, and concerns identified during the focus group meetings were used to develop a survey that was then used with a larger group of nurses.<sup>20</sup>

### *DATA COLLECTION TECHNIQUES*

A variety of techniques are used to gather data in qualitative research, including focus groups, participant observation, individual interviews, and field notes.

### *FOCUS GROUPS*

Focus groups provide an opportunity for investigators to explore the beliefs of participants and provide an avenue for previously unrecognized perceptions and concerns to be identified and addressed.<sup>21</sup> A semistructured interview guide is usually developed over several iterations with input from research partners. The questions are critiqued and revised for relevance, comprehension, and appropriateness. Focus groups are usually conducted in accessible, comfortable, and nonthreatening environments.

Focus groups consist of approximately 6 to 10 people who are purposefully gathered together to explore a topic. Focus groups use fewer resources than individual interviews or surveys and provide an opportunity for interaction and discussion among respondents. Although the process of coordinating and conducting focus groups takes time, it is rewarding for the richness of data. Positive group dynamics enhance data collection. A skillful focus group leader and moderator is needed to set ground rules and maintain a focused discussion, to facilitate participation by all members, and to reduce the influence of powerful persons within the group.<sup>22,23</sup>

Focus groups are used not only in formal qualitative research studies but also in quality-improvement initiatives. For example, focus groups are used to obtain reactions to proposed changes or proposed solutions to problems, to describe perspectives that may differ from the researcher's, to describe relationships within groups (e.g., coping strategies), to assess programs and outcomes of services, and to confirm hypotheses.<sup>9,23,24</sup>

### *PARTICIPANT OBSERVATION*

Participant observation involves the collection of data about and from participants in the participants' natural setting in a systematic and unobtrusive manner. The participant observer approaches the experience with two purposes: (1) to be present in activities appropriate to the situation and (2) to observe the activities, people, and the environment of the situation.<sup>10</sup> Participant observation may be long term and continuous, but in some settings, participant observation is noncontinuous and consists of short periods of intensive observation.<sup>6</sup> The participant observer does not initiate or precipitate action on the research topic but waits for the topic or event to emerge. Participant observers devote the first few days in the field to becoming familiar with the scene and identifying key informants, who function as important contacts with the group under study, provide background information, and serve as guides. Participant observation usually continues through the duration of the study.

## INTERVIEWS

Interviews involve a person-to-person interaction between study participants and an interviewer so that information may be elicited relative to the research. The difference between participant observation and interviewing is that the interviewer does not wait for the study participant to act or speak but obtains all information during an interview.

Interview questions for exploratory studies are likely to be open ended so as to identify sufficient information to formulate more specific questions for future phases of the research. Even with the use of open-ended questions, an interview guide or script is often used.<sup>24</sup> The use of an interview guide allows the interviewer to explore the same topics with all participants. In studies with multiple interviewers, the interview guide improves reliability. The inclusion of an interviewer script provides each participant with similar responses or "cues" from the interviewer. In some types of studies, the guide is fairly structured; in others it simply serves as a reminder of topics to discuss and may change over the course of the study.

Before the interview, the purpose of the research must be carefully and thoroughly explained following institutional review board requirements. The interviewer expects to learn from the participants and will explain to the participants the importance of any and all information they are willing to share. Audiotaping the interview session (with participants' permission) allows the interviewer to focus on the participant. Detailed field notes written during and immediately after the interview should include information about body language and other nonverbal impressions.

The focus of the interview is analogous to an inverted triangle or funnel, with the interviewer shifting from broad, general questions to narrower, focused questions. For example, an interview about respiratory protection in the emergency department might begin with questions such as "What comes to your mind when you think of the use of N95s during a bioterrorism event? Tell me about that. . ." The use of nonjudgmental, sensitive, and appropriate responses facilitates the desired one-sided interview (from the participant to the interviewer).

Any suggestion that there are "correct answers" must be avoided to reduce the participant's belief that there are socially desirable answers to the questions. Whenever possible, clarification is sought, because the researcher's interpretation may not be the one intended. For example, statements such as "What do you mean?" "I don't understand," "How did that occur?" and "I'm not familiar with. . ." may help clarify and verify participants' views. Clarifying not only facilitates understanding of meanings but also educates the researcher regarding jargon that may be used by the group under study. Probing is used when details of the participant's experience or the meanings of these experiences are needed, for example, "Can you tell me what it looked like. . . (or) . . . felt like?" or "How did you feel when this occurred?" The participants need to be provided with information about the purpose and future use of interview data.<sup>1,21,24,25,26</sup>

An example of interviewing techniques used in qualitative research can be found in a study of ethical dilemmas experienced by persons with AIDS.<sup>27</sup> Cameron used questions such as "What situation involving AIDS has caused you the most conflict about the right thing to do?" and "Is there something that you have been lying awake at night worrying about whether you should do this or that?"<sup>27</sup> During these interviews, Cameron listened to descriptions of ethical conflicts faced by persons with AIDS and their search for the "right thing to do" as it related to sexual partners, illicit drug use, death, lifestyle, finances, and healthcare.

When participants are asked to talk about incidents or behaviors that might be sensitive or threatening to the participant, researchers can ask for "shadowed data" where participants are asked to talk about these incidents or behaviors in general or report on the behavior of others, rather than themselves.<sup>28</sup> For example, instead of asking a participant to discuss reasons for why they do not comply with practice guidelines, a researcher can instead ask the participant to provide reasons why persons in similar roles or situations may not comply.

### *FIELD NOTES*

Field notes, which include nonverbal communication and environmental and other contextual factors, are records of observations. They are best written immediately after the interview and again when reading the transcription of the interview. By documenting impressions, the researcher is able to more fully represent the nonverbal influences on events.<sup>29</sup>

Field notes also should contain hunches and the researcher's working hypothesis. For example, the change in a surgeon's voice and breathing rate when responding to questions about the risk of occupationally acquired infection with a bloodborne pathogen (along with other cues) may indicate anxiety. Field notes help the researcher to review the scene mentally. During the analysis of notes, themes may be identified that will enable the researchers to develop more focused questions for future interviews or for the next phase of the research.

Field notes should include comments, remarks, or events that seem incomprehensible or unrelated to the study; their relationship to the research may become clearer with additional participants. Researcher impressions, feelings, and interpretations should be noted in the margins of the transcript. In addition, it is helpful to have transcribed field notes read and critiqued by a colleague. Field notes help minimize bias, as do outside validation from experts in the field.

### *ISSUES OF RIGOR*

For a study to have scientific merit, methodological rigor is essential. Three elements are key to achieving rigor: dependability (also called auditability), credibility (also called authenticity), and transferability (also called fittingness).<sup>29,30,31</sup>

To assess the dependability of the study is to accept the process of inquiry.<sup>29</sup> Dependability is often measured by the ability of another researcher to follow the decision trail of a researcher.<sup>30</sup> Reliability concerns are addressed by having the researcher provide clear documentation of research methods, such as interview scripts and analysis strategies, so that another researcher can follow the research procedure and decision pathway.<sup>25,30</sup> Many researchers using qualitative methods to re-interview participants, present them with transcriptions and interpretations of the initial interview, and obtain verification or clarification of the initial findings. Reliability also is enhanced if data analysis and coding procedures are reviewed by a panel of colleagues selected for their knowledge of the research topic.<sup>25,</sup>

30

It is important to ensure that the researcher's interpretations are credible. Credibility is best enhanced through the investment of sufficient time to learn the culture, to test for misinformation, and to build trust with participants.<sup>29</sup> Being aware of one's own preconceptions and bias so as to be open to what emerges from the data is vital. Field notes help minimize bias, as do outside validation from experts in

the field. Reflexive notes help to clarify the difference between the researcher's own interpretations of events and more objective data.<sup>11</sup>

Triangulation of data contributes to more credible data. One approach to triangulation is to use multiple sources to verify findings, such as interviews, participant observation, and field notes. Triangulation can be used to protect against observer or researcher bias. The researcher uses this convergence of data from multiple sources or methods for establishing the validity of a finding.<sup>25</sup> Other sources of data that may be used to support or illuminate comments made by study participants include work schedules, department budgets, memos, supply use, and historical documents. Data from other members of a research team who have obtained information from similar participants in different settings also may be used in the triangulation process.

Achieving transferability requires making connections to contexts outside of the study to see whether the conclusions would fit.<sup>29,30,31</sup> The findings need to be well grounded in the life experiences studied and to reflect their typical and atypical elements.<sup>30</sup>

Validity in qualitative research is addressed by using operational definitions that are consistent with the research question and by selecting a sample of participants who are representative of or knowledgeable about the phenomenon under study.<sup>25</sup>

## ANALYSIS

In qualitative research, data analysis techniques vary according to methodology used, and data analysis involves reducing and ordering data in a way that makes sense of the information.<sup>25</sup> Data analysis can vary from a structured approach using software that assists the researcher to code, categorize, and sort the data to a less-structured process in which the researcher reflects on the data and builds on intuition and insight.<sup>32,33,34</sup>

A simple approach to analysis involves transcription, coding, and development of themes or patterns. The interviews and field notes are usually transcribed and then analyzed. Transcripts are usually coded on a line-by-line basis. The units of coding may be single words, phrases, sentences, or paragraphs. Overarching patterns and themes are developed through the iterative process of within and across case analysis. By comparing and contrasting, the researcher begins to link themes and describe relationships. After the transcribed interview data have been classified into categories, the categories are grouped and organized into larger, more inclusive themes or patterns with the use of software programs or manually with the use of scissors and tape. Overarching patterns and themes are developed through the iterative process of within and across-case analysis. By comparing and contrasting, the researcher begins to link themes and describe patterns in the data. The findings may be verified by review by experts, the participants, or both. In qualitative research, it is not uncommon for researchers to re-interview study participants to verify the themes or categories that the researcher identified from the interview, ask questions about items mentioned by other study participants, and explore items mentioned in earlier interviews that need further elaboration.

## Limitations of Qualitative Research

The limitation of qualitative research is closely related to its strength. One of the strengths of qualitative research is that the participant's view of a situation is likely to be represented. Careful analysis of data may provide understanding of a phenomenon or lead to development of theory, hypothesis, or both. The



deliberate selection of participants within a specific context provides the opportunity to discover new phenomena and insights. Yet, this approach limits the generalization of findings to larger populations. Thus, qualitative research is not intended for generalization. Qualitative research methods are well suited for descriptive and exploratory research when little is known about a topic and flexibility is needed to discover new phenomena or find new insights into known phenomena.<sup>5</sup> Yet, they are difficult to categorize into the standardized response choices of quantitative methods. Unusual responses may provide insight, but they also make the analyses of qualitative data more time-consuming than that of quantitative data.

## Examples of Qualitative Research Applied to Practice Process and Outcome Evaluations

Process evaluation involves assessing the steps or means by which an outcome occurs. Qualitative research methods are appropriate for studying process issues because understanding processes involves detailed descriptions. Process evaluation also can be used to understand systems currently in place by identifying and monitoring factors that lead to failures and by monitoring newly implemented changes in a process. Process studies may focus on how persons adjust to change. For example, although the outcome of health services to persons with similar health problems are expected to be similar, the client's perception of the outcome may vary greatly from that of the providers or other clients. To capture this information, the clients, their personal health experiences, the meaning attached to these experiences, and the changes experienced as a result of the health services must be incorporated into the evaluation.

Similarly, the perspective of those closely involved in providing a service or product may vary greatly from those who receive or purchase the service or product. Consistent with a qualitative research approach, the researcher does not start with preconceived ideas about strengths or weaknesses of the process by which a service is provided or about the value of this service to clients. Rather, the research is conducted in a manner that allows the strengths, weaknesses, or value of a process, outcome, or both to emerge from data. In some process evaluations, continuing observation may be helpful in identifying parts of the process that are problematic.

In qualitative research, process evaluation could involve obtaining information from those responsible for decisions about programs (e.g., hospital or clinic administration), those closely involved (e.g., nursing personnel), and those who are external to the process (e.g., the community health nurse, the patient, and the patient's family). The researcher identifies the way in which the parts of the process or system work together, the relationship between the persons involved in the process or the parts of the process, and those components of the process that are working well and those that are reported to be working poorly.

Outcome evaluation in qualitative research could include obtaining information from those closely involved with providing the service and those receiving the service. Efforts are made to identify and explain the state of the institution, program, or person before the event or service. The changes that have occurred because of the event or service are noted; for example, the healthcare facility may experience increased visibility or an improvement in financial stability. Patient outcomes may be improved and physical function or physical appearance altered. Patterns of outcomes are used in evaluating programs and services.<sup>7</sup>



One finds an example of mixed qualitative and quantitative research methods used in clinical settings in a study of ventilator-associated pneumonia in the United States.<sup>35</sup> A survey was first used to determine the practices commonly used by hospitals to prevent ventilator-associated pneumonia. This was followed with a semistructured telephone interview and then face-to-face interviews of the staff to help explain the results found in the survey. The interviews identified three themes that highlighted factors that influenced the practice of preventing ventilator-associated pneumonia and how the state of the science is perceived and translated into bedside care.<sup>35</sup>

### *HUMAN IMMUNODEFICIENCY VIRUS DISCLOSURE TO SEXUAL PARTNERS*

To understand disclosure behavior among human immunodeficiency virus (HIV)-positive injection drug users, researchers used both an in-depth, face-to-face interview and then a face-to-face quantitative survey.<sup>36</sup> Both the interview and the survey covered similar HIV-related topics. The recorded interviews used a standardized interview guide of open-ended questions. The survey consisted of questions regarding specific disclosure information and a subscale of the Brief Symptom Inventory. The survey analysis supported the themes identified through the interviews. This study found that those with main partners disclosed their status sometime during the relationship, and that many did not reveal their status before the first sexual encounter with the partner. This study also found that those who are unlikely to divulge their HIV status perceived that if they were not sharing needles with these partners, they did not have a responsibility to disclose to negative or unknown partners.<sup>36</sup>

### *WORKING WITH TRAUMATIZED PATIENTS*

Focus groups were conducted with nurses regarding their perceptions of the necessary knowledge and skill sets they needed to provide care and support to refugee families as these families transitioned back to mainstream health services. After analyzing the focus group themes, the researchers found that nurses believed they had the appropriate clinical skills but needed additional training in trauma care and culturally competent care. The nurses also reported experiencing stress from the patients' trauma and/or torture experiences, as well as stress from the heavy workload, professional isolation, and their expanded roles.<sup>37</sup>

### *WORKING DURING PANDEMIC INFLUENZA*

Qualitative methods were used to describe the beliefs of nurses who would be expected to care for victims of pandemic influenza or bioterrorism events. Focus groups were held with nurses from the critical care units of three metropolitan hospitals designated as bioterrorism receiving sites. The questions moved from general beliefs about what participants believed working during pandemic influenza or a bioterrorism event would be like to questions about specific interventions that would facilitate or obstruct their ability to function in the clinical setting. The overarching theme for the recommendations was the desire for safety and security. Specific categories of needs included (1) safety amid chaos, (2) order amid chaos, (3) presence of physical and psychological support, and (4) assurance of institutional support.<sup>38</sup>

### *PATIENTS' PERCEPTION OF INFECTION WITH METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS*

By using a semistructured interview, researchers explored patients' understanding of the cause of their methicillin-resistant *Staphylococcus aureus* infection, their sense of control over the infection, the value and efficacy of the treatment plan, and perceived consequences of the infection. The patients'

perception of isolation precautions and the impact on their care and emotional state also were explored.

39

### *THE ROLE OF THE CHAMPION IN INFECTION PREVENTION*

A mixed-methods study was conducted by Damschroder and colleagues to identify and explore factors that influence the types and numbers of champions needed for effective implementation of evidence-based practices.<sup>40</sup> Following a quantitative survey, the researchers conducted a qualitative study to further explore organizational barriers and facilitators to implementing infection prevention and control practices. In the first phase of the qualitative study, telephone interviews were conducted with personnel at 14 hospitals selected for their potential to elucidate reasons that led to high or low use of infection prevention and control practices. In the second phase, site visits and interviews with personnel at six purposively selected hospitals were conducted to more deeply explore identified themes. The researchers used a conceptual framework to develop a preliminary codebook and members of the study team discussed emerging themes and coded the data using a consensus approach.<sup>41</sup> Four themes arose from the inductive approach to data analysis and included "active resistors and organizational constipators as barriers to change, clinical and administrative leaders' roles in creating a culture conducive to improving infection prevention practices, which quality improvement approaches worked best in which organization and the influential role of local champions."<sup>40</sup>

### *TENSIONS INHERENT IN THE EVOLVING ROLE OF THE INFECTION PREVENTIONIST*

A qualitative content analysis of in-depth interviews with 19 IPs at 11 hospitals across the United States was undertaken to explore the current role of the IP and to describe the ways in which IPs effect improvements in their hospitals and the facilitators and barriers that they face in their daily work.<sup>42</sup> The qualitative study was part of a larger mixed-methods study and the results of the qualitative analysis were used to refine a survey instrument used in a quantitative survey of IPs.

## Conclusions

In the six examples discussed, the methods of qualitative and quantitative research were used in an integrated manner known as mixed methods research to identify variables, develop focused interventions, establish the validity of the variables, and measure the efficacy of the interventions. The recent use of qualitative research methods in the workplace for problem solving and in the academic community for the development of knowledge has legitimized qualitative research as a valid form of inquiry. The different types of qualitative research designs are selected according to the purposes of the research. Each of these research perspectives have specific procedures for data collection and analysis.<sup>43 44</sup> In addition to the literature on quality improvement processes, to which many readers have access in the workplace, the reader is referred to the references at the end of this chapter for additional information on qualitative research design and methods.

Qualitative research is designed to reflect the whole within its context, to discover knowledge, to reformulate theory, to discover insights and meanings, and to generate understanding.

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## Feedback form

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# Research Study Design

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## Abstract

*Epidemiological studies are either observational or experimental. The choice of study design depends on the populations available for study, the frequencies of exposures and outcomes in the sample population, and the hypothesis or study question being addressed. Each study design has strengths and weaknesses and should be carefully matched to the type of data collected and the desired information. Various study designs exist, including experimental, quasi-experimental, descriptive, analytic, and others that are discussed in this chapter. Systematic reviews and meta-analyses are used to summarize evidence related to a specific research question. The critical evaluation of published research, including the type of study design used, is necessary to appropriately assign value to the conclusions of the authors of a paper.*

## Key Concepts

- Observational studies
- Descriptive studies
- Analytical studies
- Case-control studies
- Cohort studies
- Experimental studies
- Systematic reviews

## Background

Epidemiological studies are either observational or experimental. In observational studies, which may be descriptive or analytical, exposures or risk factors are not influenced by study design. In contrast, in experimental studies, certain factors or treatments that may influence the disease process or outcome are controlled as part of the study design. Both types of epidemiological studies can be used to investigate the relationship between an outcome (infection, disease progression, or death) and one or more factors (exposures or treatment).

## Basic Principles

The choice of study design should depend on the populations available for study, the frequencies of exposures and outcomes in the sample population, and the available data or participants. Each approach to study design has distinct advantages as well as limitations.<sup>1,2,3,4,5,6,7,8,9,10</sup>(See Table 20-1.)

## Epidemiological Studies

### Descriptive Studies

Descriptive studies are the simplest of observational studies describing data in basic quantitative terms, such as the number of occurrences of an outcome, perhaps broken down according to person, place, and time. They can also include case reports and case series as data sources. An example of a descriptive study is one in which describes the characteristics and infection outcomes of 100 consecutive patients who undergo a specific procedure. Such studies provide detailed descriptions of persons with a given condition or exposure; descriptive studies do not include a control group for comparison. Descriptive studies may be useful for generating rates, identifying populations at risk, or formulating hypotheses about the cause of a given outcome. However, descriptive studies cannot be used to directly test hypotheses of causality.

### Analytical Studies

Analytical studies, including cross-sectional, case-control, and cohort studies, compare individuals with and without an outcome by the presence of one or more hypothesized risk factors. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement provides recommendations of what should be included to ensure comprehensive and accurate reporting of observational studies.<sup>11,</sup>

12

### Cross-Sectional Studies

Cross-sectional studies take a snapshot of a sample population that may include the outcome of interest and the potential risk factors. For example, a researcher interested in studying the relationship between catheters and urinary tract infections (UTIs) could assess the number of patients currently in the hospital with UTIs and determine if there are more patients with catheters than without catheters. Because outcomes (both old and new) are measured, only prevalence, and not incidence, can be determined in cross-sectional studies. However, a series of cross-sectional studies can be used to estimate prevalence trends. Because risk factor and outcome data are determined simultaneously, a temporal sequence of cause and effect cannot be assessed. However, cross-sectional studies may be conducted quickly and inexpensively.

**Table 20-1** Comparisons of Epidemiological Study Designs



Study Type	Other Names	Basic Design	Advantages	Disadvantages
Descriptive	Case report	Description of one or small number of cases by person, place, and time	Quick, easy; may be useful to formulate hypotheses and identify potentially important populations	No controls for comparison, and risk factors cannot be estimated
	Case series	Description of a defined number of cases by person, place, and time	Same as case report, except rates may be estimated	Same as case report
Analytical cross-sectional	Prevalence, correlational, or survey	Outcome and potential risk factors are assessed in a population group at one point in time	Quicker, easier, and cheaper than cohort studies; useful to describe extent exposures in a population; serial cross-sectional studies can investigate changes in prevalence	Incidence cannot be determined; temporal sequence of cause and effect for risk factors and outcome cannot be determined; risk of selection bias
Case-control	Case-referent, comparison	Population of individuals with and without the outcome are identified, then compared for exposures to one or more potential risk factors	Quicker, easier, and cheaper than cohort study, especially if outcome is rare or has long latency period; useful in studying multiple possible risk factors for an outcome; if outcome is rare, a smaller study size is needed than for a cohort study	Measures exposure rate, not exposure-specific incidence; risk exposure may be unavailable or difficult to assess, subject to recall bias or inaccuracy, or biased by knowledge of outcome; selection of proper controls may be difficult; temporal sequence of cause and effect for risk factors and outcome cannot be determined with certainty
Cohort	Prospective, longitudinal	Population of individuals with and without exposure to potential risk factors are identified and followed to compare the incidence of the outcome in each group	Exposure-specific incidence of outcome can be measured directly; usually less bias in patient selection and determining exposure information than in case-control study; useful in studying outcomes with short latency period and multiple possible outcomes from exposure to a potential risk factor; provides stronger evidence for a direct causal association than do cross-sectional or case-control studies	Longer, more expensive to conduct, especially if outcome has a long latency period following exposure; if outcome event is rare, a large study size is needed; outcome determination may be biased, and individuals may be lost to follow-up
Experimental clinical trials	Controlled trial, randomized clinical trial (RCT)	Investigator assigns interventions to an experimental (or treated) group and to a control (or placebo or standard care) group (randomized allocation is the best method); experimental and control groups should be treated similarly in all respects, except for the intervention, and are followed to compare the incidence of the outcome in each group	Randomization minimizes bias; double-blinding minimizes bias in determining outcomes; RCT provides better evidence for a direct causal association than do other study designs and is the best design to use to establish efficacy of treatment or intervention	More expensive, difficult to conduct; artificial; only a select subgroup of individuals are included, which limits generalization to other groups; randomization does not guarantee similar comparison groups; if historical controls are used, they are subject to selection bias, and findings must be interpreted with extreme caution

## Case-Control Studies

Case-control studies begin with the identification of individuals who have the outcome of interest. Then a control group of individuals without the outcome is selected for comparison. For example, in a study to determine risk factors for healthcare-associated bacteremia, patients with bacteremia are identified and compared with a control group of hospitalized patients without bacteremia; medical records are reviewed to determine exposures to various factors, such as intravenous devices, invasive monitoring devices, prior infections, and immunocompetence.

Case-control studies may be undertaken in a timelier and less expensive manner than prospective cohort studies because cases may be identified retrospectively, and at least some exposure data are often available through medical record review. Case-control studies are particularly well suited for studying relatively rare outcomes or outcomes that develop over a long time after exposure. Because determination of exposure is usually made retrospectively, bias can result from difficulty or inaccuracy in recalling exposures or from the incompleteness and inaccuracy of medical records and other data sources. Sometimes the desired measure of exposure is unavailable, and surrogate measures must be substituted. The selection of an appropriate control group is critical in that control patients must not have the outcome of interest and also be similar to the cases in the potential for exposure during the period of risk being evaluated.

**Ref 0-13 Griegmes DA, Schulz KF. Compared to what? Finding controls for case-control studies. Lancet 2005;365(9468):1429–1433.**

## **Cohort Studies**

Cohort studies assess individuals with and without exposure to a potential risk factor who did not have the outcome of interest at study enrollment. The incidence of the outcome is determined during follow-up observation and compared for the exposed and the unexposed individuals. For example, a study is undertaken to follow a population of hospitalized patients with and without exposure to invasive devices to determine the association of invasive device exposure and development of healthcare-associated infections (HAIs).

Cohort studies are usually conducted prospectively, although if past exposure data are available for a population in whom current outcomes can be determined, a cohort study can be conducted retrospectively or even ambidirectionally. Cohort studies may provide more compelling evidence for causal association than do case-control studies because the exposure occurrence is established before the outcome occurs, and exposure-specific incidence of the outcome can be measured directly. Also, prospectively designed cohort studies may be less susceptible to sources of bias in patient selection and exposure determination than retrospective cohort and case-control studies.

Compared with other analytical study designs, prospective cohort studies are better suited for assessment of outcomes with a short latency period after exposure. As the latency period increases, retention of study participants becomes more difficult. When the outcome event is rare, it may not be practical to recruit a cohort of sufficiently large sample size. Because of the careful effort required to ensure high rates of even short-term follow-up, cohort studies tend to be more expensive to conduct than case-control studies.

## **Experimental Studies**

Experimental studies are prospective studies designed to compare outcomes in individuals who are assigned to an experimental (intervention) or control (placebo or standard care) group. The intervention may be a procedure, drug, or other treatment, and the comparison group usually receives a placebo, the previously accepted treatment, or, if appropriate, no treatment. Most experimental studies are

randomized clinical trials; uncontrolled trials, in which an intervention is given and patients are followed for the development of outcomes with no comparison group, are not considered clinical trials and are more appropriately classified as case series.

Randomized Clinical Trials

In randomized clinical trials (RCTs) the participants are randomly assigned to treatment or control groups to ensure that the treatment allocation is unbiased. The Consolidated Standards of Reporting Trials (CONSORT) group has established standards for the conduct and reporting of RCTs.<sup>13,14</sup> Studies that use historical controls instead of concurrent randomized controls are subject to biases in patient selection and should be interpreted cautiously.

During the follow-up period, experimental and control groups are treated the same in all other respects. On completion of follow-up observations, the groups are compared for the incidence of the outcome of interest. To avoid bias in classifying the outcome, the clinical trial ideally should also be double-blinded (i.e., neither the trial participants nor the investigators know the assigned treatment). For example, patients undergoing specific surgical procedures are assigned to groups that either receive antibiotic prophylaxis or a placebo. The identities of the antibiotic and the placebo are masked from the participants, investigators, and the persons administering the drug. Patients are followed, and infection rates are compared.<sup>15</sup>

The RCT design minimizes bias and provides the best evidence for direct causal relationships between the experimental factor and the outcome. However, RCTs are technically demanding, expensive, and usually conducted on a select subgroup of patients according to established inclusion or exclusion criteria. Because the study group may not represent the full spectrum of individuals for whom the intervention may be intended, care must be taken in generalizing the study results to other broader groups.

SYSTEMATIC REVIEWS

Systematic reviews are used to identify, collect, analyze, and summarize empirical evidence related to a specific research question. Some systematic reviews include a meta-analysis, in which statistical methods are used to integrate the results of multiple and independent studies. Systematic reviews not only describe what is currently known about a specific question but can also be used to determine what additional studies should be undertaken to address uncertainties.<sup>16</sup> The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement provides guidelines that are used to improve the quality of reporting of systematic reviews. The PRISMA Statement includes a checklist of items to be included when reporting a systematic review as well as a diagram to illustrate the flow of information in different phases of the review.<sup>17,18</sup> It is important to understand the basic steps used to conduct a systematic review in order to better evaluate the quality of these studies.<sup>16</sup> (See Table 20-2.)

Table 20-2 Steps in Conducting a Systematic Review and Meta-Analysis

Step	Goal
(1) Research question	Develop a clearly defined and focused research question
(2) Protocol	Develop and adhere to an explicit review methodology

(3) Literature search	Comprehensively search bibliographic databases; identify relevant unpublished studies; review reference lists; consult experts in the field
(4) Study selection	Use predetermined inclusion and exclusion criteria to select studies that address the research question
(5) Quality assessment	Use a scale to evaluate the quality of the included studies
(6) Data abstraction	Multiple reviewers abstract essential data to ensure accuracy and limit bias
(7) Analysis	For meta-analyses, use statistical methods to generate a summary estimate, assess heterogeneity, and assess publication bias
(8) Interpretation	Provide the results of the review in a clinical practice context

Adapted from Bent S, Shojania KG, Saint S. The use of systematic reviews and meta-analyses in infection control and hospital epidemiology. *Am J Infect Control* 2004;32(4):246–254.

## Evaluating Published Studies

The critical evaluation of published research is necessary to appropriately assign value to the conclusions of the authors of any given paper. Furthermore, it is an important component of effectively translating research findings into clinical practice.<sup>19</sup> Improved safety and healthcare can be accomplished through the application of research findings and by providing patients with evidence-based infection prevention practices.<sup>20</sup> Understanding the basic structure of typical published research papers is an initial step in the critical review process. Papers typically include an abstract and introduction, materials and methods, results, and discussion sections, as well as tables and/or figures and references.

The *abstract* is a brief summary of the purposes of the study, and of its methods, main findings, and conclusions. A structured approach to abstracts is now used by many journals.

The *introduction* presents the justification and purpose of the research in the context of the existing problem and its relationship to other current research. The research question(s) to be addressed should be clearly stated.

The *materials and methods* section describes the study population, including inclusion criteria and methods used to determine sample size as well as methods used for data analysis. Methods used for biological measures should be clearly stated.

The *results* section should directly address the research question(s) posed in the introduction. Data are presented in the text and summarized in tables and/or figures. Statistical analyses should include the appropriate measures of association, and summary measures (such as relative risk or odds ratio) and measures of precision (*p* values or confidence intervals) should be reported.

The *discussion* section includes interpretation of the major finding(s) of the study, a statement of study limitations, and suggestions for applications of the findings and future research.

## A Guide to Reviewing Published Studies

Many factors should be considered in critically reviewing an article in the scientific literature.<sup>21,22</sup> Although most journals require both editorial and expert (peer) review, the quality of published articles does vary, and it is up to each healthcare professional to critically review each article based on its merits. To

evaluate articles that report original research, appropriate questions should be asked about each component of the paper.

The following questions may serve as a basic guide:<sup>4,16,232425262728</sup>

## Introduction

Is the study question important, appropriate, and stated clearly?

## Materials and methods

- Is the choice of study design applicable to the purpose of the study?
- Is the study population appropriate for the question and adequately described?
- Are inclusion and exclusion criteria described?
- For systematic reviews, was bias introduced during study selection?
- Is the study sample representative of the population of interest?
- Are criteria used to measure the exposure and the outcome explicit?
- Were exposure outcomes of groups evaluated equally and, for RCTs, did persons blinded to the study treatment arms evaluate outcomes?
- Are the proportions lost to follow-up in each study arm described?

## Results

- Is the sample size adequate?
- Are the statistical tests appropriate for the study design?
- For meta-analyses, were findings from multiple studies pooled despite poor study quality and/or heterogeneity?
- Are factors that could have biased the results taken into account?
- Do the data that are presented in the text, tables, and figures provide an answer to the stated research question(s)?

## Discussion

- Are the conclusions that are drawn reasonable and justified given the results?
- Could alternative explanations account for the observed results?"

# Conclusions

Many study designs, observational or experimental, are available to investigators. Understanding the advantages and disadvantages of each study design should prepare the infection preventionist to critically evaluate published research studies so as to appropriately assign value to the findings.

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## **Section 3**

### **Microbiology and Risk Factors for Transmission**

# Risk Factors Facilitating Transmission of Infectious Agents

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## Abstract

*Understanding the risk factors that facilitate the transmission of infectious agents is important for preventing the spread of these microorganisms in various healthcare settings. In addition, the recognition of risk factors supports determining the need for additional interventions when patients colonized or infected with these microorganisms enter healthcare facilities. This understanding is also key for healthcare-associated infection surveillance data that adjust for certain infection risks and are used for interfacility comparison of infection rates. This knowledge then aids in the development and implementation of interventions to mitigate the transmission of infectious agents.<sup>1,2,3,4,5</sup>*

## Key Concepts

- The risk of healthcare-associated infection during patient care is related to the mode of transmission of the infectious agent, the type of patient care activity, including medications being received or procedures being performed, compliance with recommended practices, the cleanliness of the environment, the training and experience of the healthcare personnel, staffing ratios, and the patient's underlying host defenses.
- Some patient factors that increase the risk of transmission within the various healthcare settings and in the patient's own environment include immunosuppressive diseases and disorders, malignant disorders, patient's APACHE Score (Acute Physiology And Chronic Health Evaluation II Score), poor nutritional status, age, diabetes, pregnancy, travel history, occupation, residence, contact with certain pets or animals, extensive burn wounds, or trauma.
- Medical interventions have also been shown to have an influence on the patient's risk of infection including the presence of invasive devices, placement in an intensive care unit, exposure to antibiotics

or certain medications, immunosuppressive therapy, length of hospitalization, staffing ratios, experience and training of care provider for certain device-associated infections, and an increased number of healthcare personnel examinations/procedures.

- More recently, research has demonstrated that by strict compliance with recommended bundles/recommended practices for management of specific devices and in surgical care, the risk of infection can be reduced, or conversely patients are at increased risk for infection if these recommended measures are not strictly followed 100 percent of the time.
- Healthcare personnel (e.g., employees, medical staff, students, and volunteers) are at risk for exposure to microorganisms in the healthcare facility or in the home setting during home care activities. To reduce the risk, care providers must follow recommended practices (see **28. Standard Precautions**, and **29. Isolation Precautions (Transmission-based Precautions)**).
- When visitors and family enter healthcare facilities and, in particular, when they provide direct patient care, they have similar risks as healthcare personnel for transmission of infectious disease via direct contact with blood, body fluids, excretions, secretions, and the environment; via droplet transmission of agents associated with specific respiratory infections; and via unprotected airborne transmission.
- Prevention of infection in patients, healthcare personnel, and visitors requires attention to both human and environmental factors. In particular, infection risk can be reduced by adherence to appropriate infection prevention measures (e.g., hand hygiene; barrier precautions, including appropriate use of personal protective equipment; thorough cleaning of both high-touch surfaces and the routine environment). These topics are covered in detail in **27. Hand Hygiene**; **30. Aseptic Technique**; **31. Cleaning, Disinfection, and Sterilization**; and **107. Environmental Services**.

## Background

The National Nosocomial Infections Surveillance (NNIS) system was a nationwide voluntary surveillance network for healthcare-associated infections (HAIs). It was established by the Centers for Disease Control and Prevention (CDC) in 1970 to help create a national database of HAIs and improve surveillance methods in hospitals. In 1985, the goals of NNIS were broadened, and the type of information collected was increased to more completely characterize infections and permit identification of potential risk factors.<sup>6,7</sup>In 2005, NNIS and the other surveillance systems at the CDC (the Dialysis

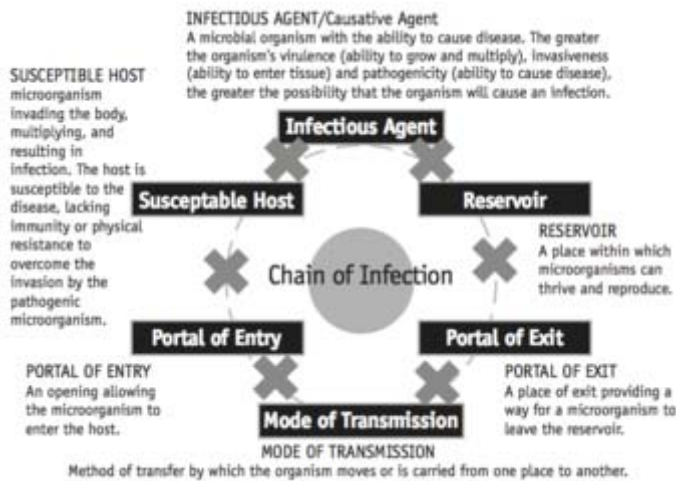
Surveillance Network [DSN], and the National Surveillance System for Healthcare Workers [NaSH]) evolved into the National Healthcare Safety Network (NHSN).<sup>8</sup>The voluntary members of NHSN report their facility data for aggregation into this national healthcare infection database. The goals of NHSN are to provide an estimate of the magnitude of HAIs; identify and provide data trends; assist inter- and intrahospital comparisons with risk-adjusted HAI data that can help with local performance improvement and quality activities; help member facilities develop surveillance and analysis methods to help identify patient safety problems; and encourage prompt intervention to improve outcomes. In February 2013, NHSN released their latest standardized infection ratio (SIR) report for surgical site infections and device-associated infections; in April 2013, they released their latest report with infection rate data on device-associated infections.<sup>9</sup>Currently, NHSN has replaced NNIS as the gold standard for sharing HAI data, benchmarking for healthcare facilities, and providing validated parameters for the risk model utilized.

## Basic Principles

A model used to understand the infectious disease process is often called the chain of infection. Understanding the components of the chain of infection is critical to determining risks of infection and interventions to interrupt the disease process to prevent or mitigate transmission. This allows staff to identify and protect vulnerable patients and to take precautions to protect themselves. Each link, in sequential order, must be present for an infection to occur (see Figure 21-1).

**Figure 21-1.**

Components of the infectious disease process. Modified source: Centers for Disease Control and Prevention. *Principles of epidemiology*, 2nd ed. Atlanta: U.S. Department of Health and Human Services, 1992. Available at:



[http://www.cdc.gov/osels/scientific\\_edu/ss1978/lesson1/Section10.html](http://www.cdc.gov/osels/scientific_edu/ss1978/lesson1/Section10.html).

[View Image](#)



## Risk Factors for Infection Transmission

### Infectious Agent

There are several characteristics that influence the transmissibility of an organism and its ability to cause disease:

- Virulence: the ability to grow and multiply
- Infectivity: the ability to enter tissues
- Pathogenicity: the ability to cause disease
- Duration of exposure: the length of time the person is exposed to the organism
- Size of inoculum: the number of organisms needed to cause disease

### Reservoirs

All organisms have a place where they can exist and reproduce that facilitates their transmission. These include:

- Humans: *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Clostridium difficile*
- Animals: pigs (swine - *Influenzae*), birds (avian - *Influenzae*), dogs (parasites - worms), turtles (*Salmonella*), bats (rabies)
- Insects: *Babesia*, malaria, Rocky Mountain spotted fever, West Nile virus
- Food: *Cryptosporidia*, *Cyclospora*, *Salmonella*, *Listeria*
- Environment:
  - Internal: inanimate objects (*Clostridium difficile*), dust (*Aspergillus*), water (*Legionella*)

- External: soil (*Coccidioides*– Valley Fever), plants (*Sporothrix*)

## Portal of Exit

Next in the chain of infection, an infectious agent needs a means to exit from its reservoir.

- Respiratory: sneezing, coughing, biting
- Gastrointestinal: feces
- Weather: wind, rain
- Natural disaster: earthquake
- Inanimate objects: contaminated
- Skin/integumentary

## Mode of Transmission

Transmission-based Precautions have been designed to address the specific routes of transmission for a variety of diseases, and the updated isolation guideline from the Healthcare Infection Control Practices Advisory Committee (HICPAC) was published in 2007.<sup>10</sup> The new guidelines are largely the same recommendations as the 1996 document, but with a couple of critical changes:

1. The recommendation to don the indicated personal protective equipment (gowns, gloves, mask) upon "entry into the patient's room" for patients who are on contact or droplet precautions because the nature of the interaction with the patient cannot be predicted with certainty, and contaminated environmental surfaces are important sources for transmission of pathogens.<sup>10</sup>
2. The guidance on the application of precautions in settings other than just acute care (e.g., hospice, home health, ambulatory, long-term care, etc.).

The most recent HICPA isolation guidelines are addressed in detail in **28. Standard Precautions** and **29. Isolation Precautions (Transmission-based Precautions)**.

## Portal of Entry

The portal of entry is any type of opening that allows the infectious agent to enter the patient's body to cause an infection or colonization. This could be the result of patient care activities, a procedure, an indwelling device, ingestion, inhalation, or absorption through the skin or mucous membranes. Examples include:

- Indwelling urinary catheters
- Intravascular devices
- Ventilators
- Surgical procedures performed within or outside the operative suites
- Contaminated food
- Contaminated water
- Coughing in the face of a healthcare provider
- Tracheostomy care
- Dressing changes

## Susceptible Host

There are many factors that can render a person a susceptible host, from physiologic to environmental to occupational. Some factors can be controlled, whereas others require the implementation of interventions to mitigate their effect.

### **Anatomic/Physiologic Factors**

The immune system is a very complex system of which we still do not understand all of its functions and mechanisms. What we do know is that any breach in this system can wreak havoc in the ability of a person to prevent or fight infections. Included in this category are:

- Specific and nonspecific immunologic deficiencies
- Risk of aspiration due to functional or chemical disorders (e.g., GERD), oropharyngeal incoordination, neurologic disease
- Weakness or fatigue in the pulmonary musculature
- Gut dysmobility
- Trauma
- Extensive third-degree burns
- Malignant disorders
- Asplenia
- Urinary retention, incomplete evacuation with or without vesicoureteral reflux
- Diabetes
- Malnutrition/poor nutritional status
- Age
- Gender

### **Medical Intervention Factors**

- Surgical/invasive procedures: type, duration
- Indwelling devices
- Medications
- Stays in a critical care unit
- Length of stay
- Experience and education of healthcare providers
- Staffing ratios
- Repeated/number of examination by healthcare providers
- Teaching institutions
- Appropriate device cleaning, disinfection, and sterilization

### **Environmental Factors**

- Stay in a room previously occupied by a patient with a multidrug-resistant organism (MDRO) or *Clostridium difficile*: Studies have shown significant transmission risk to subsequent occupants in a room that previously housed a patient with an MDRO or *C. difficile*.
- Type of disinfectant used
- Compliance with hand hygiene, use of barriers

- Thoroughness of environmental and equipment cleaning and disinfection
- Contact with pets/animals

## Occupational Exposure

Healthcare personnel (HCP) (i.e., employees, medical staff, students, and volunteers) are at risk for exposure to microorganisms in the healthcare facility or in the home setting during home care activities.

11,12,13,14,15,16,17 Airborne transmission is a particular concern for HCP when they enter a home or

environment where someone has an airborne disease. These organisms can remain in the air for significant periods of time and, thus, personnel need not be in immediate contact to become infected. Personnel may still be exposed, even if they are not providing direct patient care, if the air is contaminated with airborne pathogens such as measles and tuberculosis (TB). Airborne transmission of microorganisms is a potential for personnel in the following situations:

1. A patient with an airborne-transmitted disease is not promptly recognized and isolated in a negative air pressure isolation room (airborne infection isolation) (e.g., TB transmission).<sup>18</sup>
2. An employee does not use an appropriate respiratory protection (i.e., N95 respirator) when caring for a patient in an isolation room.<sup>18</sup>
3. Another healthcare provider has an unrecognized airborne infection (e.g., incubating chicken pox) and reports to work.<sup>10,11,19</sup>
4. A visitor is infected with an airborne-transmitted disease, such as measles.<sup>20</sup>
5. Ventilation is inadequate and carries air from an isolation room to other areas of a facility, resulting in airborne transmission of diseases (see **29. Isolation Precautions (Transmission-based Precautions)** and **95. Tuberculosis and Other Mycobacteria**).<sup>18</sup>
6. The ventilation system is contaminated with an infectious agent, such as *Legionella* species.<sup>21,22,23,24,25,26</sup>

The potential for contact with blood, body fluids, and other potentially infectious materials, including secretions and excretions, most often occurs for the HCP during direct patient contact (by the medical and surgical staff or during nursing care, respiratory care, radiology, and physical therapy) or in the laboratory. Other employees, such as those in social services and pastoral care, recreational therapy, or volunteers, are at lower risk for exposure based on their routine job tasks and activities. Direct contact can occur in the following situations:

1. Contact with blood and body fluids occurs without appropriate barrier precautions (e.g., for hepatitis C or herpes simplex virus [from oral secretions]).<sup>11,27</sup>
2. Personal protective equipment malfunctions or breaks.
3. HCP fails to identify risk and the need for personal protective equipment (e.g., a patient has herpes zoster on the back and the need for gloves is not communicated to the respiratory therapist before chest physical therapy is initiated, resulting in an exposure; or the therapist fails to use gloves to prevent transmission of vancomycin-resistant *Enterococcus*).<sup>28,29,30</sup>
4. Inadequate hand hygiene or failure to use personal protective equipment such as gloves and gowns allows transmission of enteric illnesses, such as hepatitis A or methicillin-resistant *Staphylococcus aureus* (MRSA) or *C. difficile* spores via the hands of HCP.<sup>31,32,33</sup>



Indirect contact with contaminated food, water, or supplies may occur for the healthcare provider and potentially result in disease transmission in the following situations:

1. Sharps and biohazardous waste are not disposed of properly, allowing percutaneous injuries or mucous membrane exposures to occur.<sup>11,34</sup> The risk of transmission of bloodborne pathogens associated with needlestick exposures also increases if appropriate postexposure prophylaxis is not appropriately initiated.<sup>35,36</sup>
2. Food and water supplies used by the employees are not prepared and maintained according to sanitation standards, including storing at the appropriate temperature.
3. An HCP can be infected by the indirect route if they perform inadequate hand hygiene or do not wear the proper personal protective equipment when handling contaminated equipment or when in a contaminated environment, such as a room of a patient with *C. difficile* or severe acute respiratory syndrome.<sup>7,37</sup>

### **Visitors and Family Members**

Visitors and family are at risk for exposure to microorganisms when they visit healthcare facilities or provide care in the home. Airborne infection transmission is a concern because the risk is difficult to minimize since the agents may be unknown and are hard to detect. The visitor may not have had direct contact with the infected person or source; therefore, no one recognizes that an airborne exposure may have occurred, and the appropriate prophylaxis is not given. Airborne transmission of microorganisms is a potential for visitors in the following situations:

1. A patient with a respiratory-transmitted disease is not promptly recognized and isolated in a negative air pressure room (e.g., a child with measles is not triaged quickly in an emergency care setting and remains in the area, exposing others in the waiting room).<sup>20</sup>
2. A visitor does not use respiratory protection when entering an airborne infection isolation room.<sup>18</sup>
3. Another visitor has an unrecognized airborne-transmitted disease; for example, a child in the prodromal stage of chicken pox in an outpatient pediatric clinic or during sibling visitation in the hospital.
4. Ventilation is inadequate and carries air from an isolation room to other areas of the facility, as has been reported in multidrug-resistant TB outbreaks.<sup>18,38</sup>
5. The ventilation system harbors an infectious agent.

When visitors and families provide direct patient care, they have the same risk as HCP for transmission of infectious disease via direct contact with blood, body fluids, excretions, and secretions. The potential for exposure during these activities would be similar to that of the healthcare providers. Family care providers and visitors have a risk similar to that of HCP for transmission of an infectious agent through indirect contact if they handle contaminated patient care equipment or if they ingest contaminated food or water while in the healthcare setting.<sup>39</sup> Education of these care providers to minimize the risk is critical to protect them from exposure.

### **Practices to Decrease the Risk of Transmission**

An infection prevention committee should establish and monitor compliance with and the effectiveness of the facility's infection prevention and control policies and procedures. Patient care practices, especially specific high-risk patient care procedures, should be monitored. The infection risk of certain patient care procedures can be significantly reduced by adherence to appropriate infection prevention measures

(e.g., hand hygiene, barrier precautions, Institute for Healthcare Improvement [IHI] device-specific bundles).<sup>7,15,16,17,18,23,31,40,41,42,43,44</sup>

High-risk procedures include:

1. Intravascular access, especially central lines<sup>41,45,46</sup>
2. Mechanical ventilation<sup>40,45</sup>
3. Surgical and invasive procedures<sup>31,45</sup>
4. Intracranial monitoring
5. Parenteral nutrition (e.g., hyperalimentation)
6. Urinary tract instrumentation, especially indwelling catheterization<sup>31</sup>
7. Extracorporeal membrane oxygenation<sup>47</sup>
8. Ventricular assist devices (used for maintaining a patient who is awaiting a heart transplant).

For more information, the reader should refer to chapters in this text that address specific high-risk procedures, including **33. Urinary Tract Infection**, **34. Intravascular Device Infection**, **37. Surgical Site Infection**, and **55. Endoscopy**.

### ***Surveillance Activities***

The 1985 Study on the Efficacy of Nosocomial Infection Control (SENIC) found that active HAI surveillance and the reporting of infection rate data to associated HCP resulted in a reduction in the occurrence of HAIs. For example, surgical site infections (SSIs) are reduced when a surgeon-specific, healthcare-associated SSI rate is provided to the surgeon; similarly, the urinary tract infection (UTI) rate is decreased when the unit-specific healthcare-associated, urinary catheter-associated UTI rates are reported to the specific nursing unit. The Joint Commission (TJC) National Patient Safety Goal (NPSG) relating to performance stresses the need for feedback and communication of surveillance activities, not only to the direct patient care provider, but also to administrative leaders and governing boards.<sup>48</sup>

Focusing on prevention and providing outcome surveillance data to all is a prime risk reduction strategy.

49

### ***Patient Placement***

The physical space requirements for patient care areas and hospital rooms set by state and federal codes mandate adequate spacing between patients to prevent crowding and reduce the risk of microorganism transmission. Policies should exist to ensure assessment of unique patient needs regarding patient placement based on their risk for exposure. Patients who are at increased risk for infection because of immunosuppression may require separation by private room or cohorting away from infected patients (e.g., patients with draining lesions).<sup>10</sup> Patients infected or colonized with

epidemiologically significant organisms, such as vancomycin-resistant enterococci (VRE) or MRSA, may be separated from other patients as part of an overall control plan.<sup>10,50,51,52</sup> Patients with airborne infectious diseases, such as TB or measles, should be cared for in a negative air pressure isolation room.<sup>10,31</sup> Although a private room is desirable, patients with the same airborne disease may share a room if there is no clinical contraindication.

Cohorting of patients infected or colonized with a common organism by room or personnel assignments can reduce the risk of transmission of infectious agents to other noninfected patients.<sup>10</sup> The CDC

isolation guidelines provide guidance for cohorting patients using the following criteria:

1. Common risk factors, such as infants born during the same time frame or patients admitted with similar infection (e.g., *Salmonella*).
2. Common exposure to a communicable disease, such as a ward for those exposed to varicella, if individual private rooms are not available and patients are not immunosuppressed. It must be noted that it is preferable to isolate each patient individually, rather than as a cohort. Placing more than one patient in a room for cohorting exposed patients could potentially lead to an ongoing exposure if one patient develops the disease and another does not, thus creating a new exposure episode for the second patient.
3. Prevention of contact between patients known to be infected or colonized with epidemiologically significant organisms and patients who are newly admitted or not harboring the organism; cohorting in this manner is often used as an outbreak control measure.

## Patient Hygiene

One goal of personal hygiene for the patient is related to infection prevention: namely, reduction of the microbial load of the skin and maintenance of the well-being of mucous membranes, such as the mouth and vagina.<sup>53,54,55</sup> The following are examples of activities that may reduce the bio load:

1. Washing from clean to less-clean areas using clean washcloths to prevent cross contamination.
2. Preoperative showering using antimicrobial soap.<sup>56</sup>
3. Washing with antimicrobial soaps, such as chlorhexidine gluconate, to reduce carriage of resistant organisms, such as MRSA.
4. Active surveillance culturing for epidemiologically significant organisms based on facility's epidemiology.<sup>10,45</sup>
5. Encouraging or assisting patients in maintaining good oral hygiene<sup>58</sup> and caring for the mouth to reduce the risk of mucositis in the immunosuppressed.<sup>57</sup>
6. Encouraging good genital area cleansing.
7. Good hand hygiene practices using soap and water or alcohol-based hand rubs, as appropriate.<sup>58</sup>
8. Treatment of remote site infections prior to surgery.<sup>56</sup>
9. Additional personal risk reduction strategies include smoking cessation or weight loss if possible and appropriate.<sup>56</sup>

## Patient Education

A knowledgeable patient can be an active participant in reducing infection risks. Patients should be taught the concept of standard barrier precautions to educate them concerning exposure to blood and body fluids, including excretions and secretions. They should also be instructed about the proper disposal of contaminated items, such as tissues and sanitary napkins. Basic hygiene should be taught to patients who need it, including the use of toilet facilities and respiratory hygiene/cough etiquette. This is particularly important for children, for patients with an altered mental status, and often for recent immigrants from developing countries, recognizing cultural differences and individual country risk factors. Patients can participate in their own care and perhaps lower their infection risk through an increased understanding and improved practice of aseptic principles. The 2013 NPSG 7 emphasizes the importance of patient education concerning key topics such as SSI prevention, prevention of central line-

associated infections, and the management of resistant organisms.<sup>48</sup>When indicated, patients should be taught the following:

1. Hand hygiene, including when to use soap and water or alcohol-based hand rubs.
2. Barrier techniques to prevent exposure to blood and body fluids, and proper handling of sharps and use of safety devices as part of their care.
3. Mode of transmission of microorganisms from one area of the body to another.
4. Location of portals of bacterial entry that are associated with therapeutic and diagnostic measures to reduce the risk of inadvertent contamination of intravenous sites, dialysis sites, or surgical sites.
5. Symptoms associated with infection and the need to report them to healthcare providers.
6. Effective breathing and coughing techniques to be used postoperatively to reduce pulmonary complications.
7. Cough containment to reduce transmission of airborne pathogens, including teaching respiratory hygiene/cough etiquette.
8. Principles and methods for disposal of sharps and medical waste.
9. Specific patient care procedures the patient will be performing at home.
10. Discharge planning that is relevant to the patient's medical condition and individual needs.

Patients are being discharged from the acute care setting more rapidly than in the past. Coordination of the discharge process, including education of the patient and family, the home care agency, and the long-term care facility, is essential to reduce infection risk and ensure the continuation of consistent care. Communication between every service/professional along the continuum of care is critical to identify risks and improve patient outcomes. Invasive devices and surgical sites may require postdischarge care. When indicated, information should be provided on:

1. The care of respiratory devices, including (a) cleaning and disinfection of reusable respiratory care equipment (including humidifiers), and (b) care of tracheostomies and suctioning techniques.
2. The care of intravascular catheters, including (a) site care and maintenance, (b) line changes, (c) medication storage and administration, (d) proper access of the device, and (e) signs and symptoms of infection or malfunction.
3. The care of urinary catheter systems, including (a) indwelling and suprapubic catheterization techniques and maintenance, (b) self-catheterization, (c) cleaning and disinfection of urinary catheterization equipment, (d) other urinary management techniques, and (e) signs and symptoms of infection or malfunction.
4. The preparation, care, administration, and storage of enteral tube feedings.
5. Wound care and sterile dressing techniques in addition to the signs and symptoms of infection.
6. Standard barrier precautions for the patient and care providers.
7. The management and handling of biohazardous waste, including sharps.
8. Special precautions for specific communicable diseases, such as tuberculosis, the role of the public health department in patient follow-up, and administration of direct observation therapy, often referred to as DOT.<sup>18</sup>
9. Adherence to and importance of completing all treatment modalities, including antimicrobial therapies, and following the medical/nursing team's instructions.
10. Signs and symptoms that should be reported to the healthcare provider.

## ***Personnel Practices***

TJC emphasizes the importance of preventing infections in HCP and has provided standards to facilitate occupational health programs to prevent the transmission of infection to and from patients and staff. For

additional information regarding the standards, go to <http://www.jointcommission.org>.

Occupational health policies designed to reduce the risk of infection transmission to patients, fellow employees, and visitors should establish the following guidelines:

1. Immunization of personnel must be required and available.<sup>48,59,60,61</sup> Influenza vaccination for HCP is an important strategy for both HCP and patient safety.<sup>61</sup>
2. Restriction of HCP with a communicable disease or infectious process, such as diarrhea, group A streptococcal infections, conjunctivitis, draining dermatitis or exudative lesions, active tuberculosis, and possible infectious rashes. Reasons for work exclusion must be clearly outlined and actively made available to HCP and their supervisors.
3. Assignment of patients to be cared for by immune HCP (e.g., only employees with immunity to varicella should be assigned to work with patients who have chicken pox or herpes zoster).
4. Protocols should be created for evaluation and follow-up of employee exposure to infectious diseases.<sup>11,61,62,63</sup> These include: (a) employee hygiene practices, such as proper hand washing/hand hygiene, proper attire, and general cleanliness; (b) employee education to increase understanding and knowledge of their role in infection prevention and specific patient care practices that may decrease risks for patients; (c) monitoring of compliance with established infection prevention protocols and provision of feedback to promote an effective prevention and control program; (d) appropriate use of safety devices; and (e) appropriate patient/nursing staff ratios.<sup>64,65,66</sup>

### ***Environmental, Engineering, and Dietary Practices***

Housekeeping procedures designed to reduce bioburden and remove contaminated blood or body fluids can reduce the risk of transmission of an infectious agent from an environmental reservoir. Selection and use of equipment and products appropriate for the task is important.<sup>67,68,69</sup> (See **31. Cleaning, Disinfection, and Sterilization**.) Examples of these practices include safe handling and removal of biohazardous trash and sharps, cleaning and disinfection procedures for patient rooms, operating room end-of-case cleaning, routine cleaning of ice machines, and removal of food from patient care areas after meals. With the increased risk of resistant organisms (e.g., *C. difficile*), effective and thorough cleaning of high-touch surfaces in addition to the routine environmental cleaning is critical to reduce the transmission of these organisms from contaminated environments.<sup>24,28,31,47,68</sup>

Engineering procedures to establish and maintain water, ventilation, and sewage systems that meet regulatory standards can reduce the risk of infections. Preventive maintenance is an important part of ensuring the quality of these systems, and critical features of systems are listed in the HICPAC environmental guideline.<sup>68</sup> The American Institute of Architects' 2006 guidelines also provide parameters for building a safe environment.<sup>69,70</sup> Thorough infection prevention risk assessments for construction and renovation projects will provide measures/interventions to prevent and/or reduce infection risk during a project. Once measures are established for a project, frequent monitoring to ensure compliance is an essential practice to control risk. (See **107. Environmental Services**.)

Dietary procedures to establish sanitary practices for the preparation, distribution, and storage of food reduce the risk of foodborne infectious agent disease. Basic components should address local public health regulations, including maintenance, temperature documentation, and cleaning of freezers, refrigerators, and dishwashers; cleaning and sanitization of eating and cooking utensils; and adherence



to food preparation standards. Facilities should also have policies assuring food safety in patient care areas, including the amount of time food may be left at a bedside and the monitoring of food refrigerators.

Patient care equipment standards must include standards for cleaning, disinfection, and sterilization of reusable items to reduce risk of transmission of microorganisms from patient care items to the patient. Standards shall also include procedures for distribution and storage of patient care equipment, as well as recall procedures for products identified as unsafe or inadequately processed or sterilized. Refer to **31. Cleaning, Disinfection, and Sterilization**, and the HICPAC *Guideline for Disinfection and Sterilization Practices, 2008*.<sup>71</sup>The Association for Professionals in Infection Control's (APIC) *MRSA*

*Elimination Guide and the Elimination Guide for Clostridium difficile in Healthcare Settings* provides sample checklists that have been shown to improve overall cleaning practices and especially the cleaning and disinfection of high-touch surfaces.<sup>32,68</sup>

## Visitor Guidelines

Visitors are a potential source of infection and are at risk for exposure if clear directions and signage are not available when a visitor enters the healthcare setting. Does the signage at the entrance of the facility identify restrictions for visitors, or do visitors not learn of restrictions until they reach the patient care unit? Each facility should establish and teach the following guidelines to minimize the risk of disease transmission:

1. Identify areas of the facility where visiting is allowed.
2. Clearly post precautions that visitors must take if visiting a patient in a high-risk area or isolation (e.g., hand washing, wearing personal protective equipment), or if they are being trained to assist in providing care.
3. Teach respiratory hygiene and cough etiquette. Be sure to provide the essential supplies to promote compliance, such as tissues, masks, alcohol-based hand rubs, and bags for disposal of used tissues.
4. Provide warning signs for exclusion of visitors with communicable disease, and, possibly, implement additional visitor restriction during times of high levels of community illness, such as influenza epidemics.
5. Teach parents the key tenets of safe sibling visitation guidelines, including screening for active or potentially incubating communicable diseases.

## Relationship between Patient Care Requirements and Infection Risk

Host factors that influence infection risk are related to specific and nonspecific immune system components and to the number and type of microorganisms introduced into a body system. An increased need for healthcare provider intervention is also associated with an increased risk for infection. Some of the patient factors that increase the risk of infection include immunosuppressive disease and disorders, autoimmune diseases, malignant disorders, poor nutritional status, age, diabetes, extensive burn wounds, or trauma.<sup>72</sup>In addition, particular medical interventions have been shown to have an influence on the patient's risk of infection: the presence of invasive devices (e.g., indwelling urinary catheters and intravenous equipment), placement in an intensive care unit (ICU), exposure to antibiotics, immunosuppressive therapy, steroids, length of hospitalization, and an increased number of HCP examinations/procedures (e.g., increased number of vaginal exams during labor).<sup>72,73,74</sup>

Care requirements, as measured by severity-of-illness classifications, may be useful in healthcare-associated risk stratification and are influenced by the following patient conditions.<sup>71,72,73,74,75</sup>

1. Ability to ambulate
2. Mental alertness
3. Ability to perform routine basic activities of daily living
4. Need for assistance to maintain normal body system functions

Readers are advised to consult general medical and nursing textbooks for specific information on activities designed to support normal body function.

## **Staffing Ratios**

During the past decade, the relationship between staffing and the patient's risk of HAIs has been explored by many groups.<sup>64,65,66</sup> Stone et al.<sup>66</sup> systematically reviewed the related literature ( $n = 42$  articles). The review included bloodstream-related reports ( $n = 18$ ; 43 percent) and nurse staffing ( $n = 38$ ; 90 percent). Of those studies, only seven (18 percent) did not find a statistically significant association between nurse staffing variable(s) and HAI rates. Increased HAI rates were also associated with use of nonpermanent staff ( $n = 4$  studies,  $p < .5$ ). Mixed results were noted in three studies that addressed infection preventionist staffing and the risk of infection. Two studies found that physician staffing was not found to be associated with patients' HAI risk. Despite the variety of methods and the differences in operational definitions used for both staffing and HAI, the trends were apparent. More precise understanding is needed regarding staffing and staff training and the role these factors play in preventing HAIs. Likewise, in an era of increased monitoring and feedback and a culture of zero tolerance, more data on staffing ratio of the infection prevention team and its contribution to risk reduction for HAIs are needed.<sup>31</sup>

## **Conclusions**

Prevention of infection in patients, staff, and visitors requires attention to both human and environmental factors. Clear and comprehensive protocols, with regular monitoring for compliance, can promote a safe patient care environment and optimal outcomes. The infection preventionist should consult a variety of sources for updated information on infection risks, including the NHSN<sup>1,2</sup>; TJC sources, including core measures and the NPSG<sup>48</sup>; IHI<sup>45</sup> reports and relevant studies published in the professional peer reviewed literature; and recommendations from HICPAC.

Nursing staff ratios per patient have also been shown to influence the risks of infection during patient care. More data relating to appropriate ratios are critical so HCP and management can clearly understand how to best use both the financial and human resources that are being stretched so thin in today's economic environment. Clearly, more data and research are needed to provide staffing ratios and other measures that establish the optimal care setting for reducing infection risk.

## **Future Trends**

The NHSN is providing new opportunities to promote patient and HCP safety by providing protocols for monitoring adverse events associated with devices, procedures, and medications; feedback of comparative data for performance improvement; and access to prevention tools, lessons learned, and



best practices. The expanded scope of NHSN provides new data throughout the hospital, instead of strictly the intensive care unit setting. These new data provide a stage for more insight into patient care practices and opportunities for improvement in light of the increasing acuity of hospitalized patients.

Better methodologies for tracking device-associated infections throughout the continuum of care are needed. The role and capacity to provide post discharge surveillance for SSIs and other procedures also need more research to validate methodologies and determine the resources needed to accomplish comprehensive surveillance throughout the continuum of care. As the length of stay decreases and patients are managed via ambulatory care settings or home care, prevention strategies and risk reduction activities in these settings will be critical to preventing all HAIs, regardless of the setting.

## International Perspective

Although many risk factors may be specific to a country, as well as the environment of care, compliance with best practices can promote improved outcomes, regardless of the environmental or organizational constraints. Expansion of benchmarking to include international audiences and aggressive sharing of best practices and lessons learned will provide wider access to prevention strategies. The literature has multiple reviews that address prevention issues, including risks in international settings. Translating knowledge from the United States and other developed countries into strategies that will be successful in developing countries will be critical for universal risk reduction. The World Health Organization (WHO) has begun that process. In October 2005, WHO launched the Global Patient Safety Challenge: Clean Care Is Safer Care, which addresses hand hygiene; clean, safe water; blood safety; injection and immunization safety; safer clinical practices; and, finally, sanitation and waste management. WHO is employing proven low-cost strategies and working diligently to reduce the burden of HAIs.<sup>76</sup> Perhaps this simple and practical approach will bring new insights that are applicable for all.

## Supplemental Resources

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# Microbial Pathogenicity and Host Response

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## Abstract

*Infection results when an imbalance occurs between the mechanisms that microorganisms employ to induce infection and the complex physiological response systems that are employed by a host to prevent such infections. Infection can be distinguished from colonization, which is when a microorganism occupies an ecologic niche in a host, grows, but does not overcome host resistance or cause invasive disease. In the past decade, increases in microbial virulence induced by changes in exotoxin production or surface antigenic construction have led to a better understanding of determinants of virulence. We have also come to understand the interactions within the immune system that serve to foster integration of host defense and how human immunodeficiency virus, the immune-altering prototypic infection of the 20th century, modifies and defeats those defenses. Additionally, we are now able to distinguish between those elements of natural defense, sometimes referred to as innate immunity, which are activated by cell injury or death, and adaptive immunity (cellular and humoral), that can be enhanced and have the property of immunological memory. In many circumstances, we can enhance or support a state of vigorous adaptive immunity and terminate or prevent infection. Understanding these defense mechanisms is essential to the design and implementation of effective infection prevention and control programs in healthcare settings.*

## Key Concepts

- Virulence, commonly recognized as the measure of a microbe's ability to invade and create disease in a host, is determined by characteristics that relate to the favored site of invasion, disease induction, and avoidance of host defense mechanisms of resistance.
- The initial element in virulence is the ability of an organism to survive in the external environment during transit between hosts.
- The second element in virulence is a mechanism for transmission to a new host.

- When a microorganism reaches a favorable site for inducing disease, it must adhere to the structure that it will infect.
- Once a pathogen has attached successfully to a site for infection, it must have mechanisms for proliferation.
- Following local proliferation by a pathogen, elements of virulence favor invasion and dissemination.
- One limb of the adaptive immune response is called the *cell-mediated immunesystem*, which is induced, mediated, or regulated by T-lymphocytes and mononuclear phagocytes. If the cell-mediated immune system is altered, defense against virus, mycobacterial, and fungal infections, among others, can be seriously compromised; antibody production may even be adversely affected by effects on T cells that regulate the function of antibody (humoral-see below) immunity.
- A cellular immune response is initiated when a foreign substance, such as a bacterium, virus, or other foreign antigen, is taken up by large phagocytic cells of various types (macrophages in tissues, Langerhans cells in skin, and follicular dendritic cells in lymph node germinal centers).
- T-lymphocytes comprise a number of families that are highly specific in function.
- Cytokines (including lymphokines from lymphocytes) are substances liberated by various cell lines that have specific structures and biological activities.
- In contrast with the cell-mediated immune system, humoral immunity is expressed by proteins called *antibodies*. These are principally within the bloodstream, but secretory antibody is also present in oral secretions, tears, intestinal contents, breast milk, prostate, and the female reproductive tract.

## Principles Of Microbial Pathogenicity And Host Response

### OVERVIEW<sup>1,2,3,4,5,6,7</sup>

Virulence is the measure of a microbe's ability to invade and create disease in a host and is determined by characteristics that relate to the favored site of invasion, disease induction, and avoidance of host resistance.

The initial element in virulence is the ability of an organism to survive in the external environment during transit between hosts. Successful pathogens possess ecological niches in the environment, such as blood in the case of bloodborne pathogens (e.g., Hepatitis B and C, human immunodeficiency virus [HIV], and cytomegalovirus). *Mycobacterium tuberculosis* possesses a lipid coating in its cell wall and collects dried proteins from sputum to protect it against death by drying in air. *Pseudomonas* has the capacity to extract minute quantities of nutrients from water, including dead microorganisms, and survive in aqueous environments for months. *Clostridium difficile*, the etiological agent of pseudomembranous colitis, can revert to a spore state that is very resistant to drying, chemical agents, and heat such that it can survive for months in the environment, germinating to its actively growing form after host invasion.

The second element in virulence, as it is understood, is a mechanism for transmission to a new host. Many organisms are carried successfully from host to host within vectors, such as West Nile virus, yellow fever virus, and plasmodia (malaria) in mosquitoes, and *Borrelia burgdorferi* (Lyme disease), and *Rickettsia rickettsiae* (Rocky Mountain spotted fever) in ticks. Effective insect vectors transmit pathogens by injecting material from salivary glands or by defecation into sites of penetration of host skin. A few viruses, such as respiratory syncytial virus (RSV), can survive on environmental surfaces, such as bed rails and be transmitted by hands to mucous membranes. Some bacteria possess mechanisms of motility, such as *Escherichia coli*, that enable them to ascend a flowing stream of urine from the urinary bladder to the kidney and cause pyelonephritis. When a microorganism reaches a favorable site, it must

adhere to the structure in order to initiate an infection. Electrostatic negative charges on most bacteria favor adherence to human cells, and specific adhesins on bacterial surfaces favor attachment to sites of infection. Such attachment may be complex, such as the interaction between CD4 receptors (CD is derived from cluster-of-differentiation and refers to the assigned designation by the scientific community) on HIV- and CD4-bearing lymphocytes, then subsequent attachment of glycoprotein (GP) 120 to a specific site on the lymphocyte, followed by attachment of GP41 on HIV to its respective receptor on the lymphocyte. Each step is followed by conformational changes in the virus coat or capsid to facilitate the next step. Binding to foreign bodies, such as intravenous or indwelling urinary catheters by bacteria, often involves a bacteria-secreted glycocalyx (a slimy covering secreted by some bacteria). Bacteria may also form biofilms: self-produced, polymeric conglomerations of extracellular DNA, proteins, and polysaccharides that confer resistance against different environmental stresses, including immune responses and antimicrobial agents. This encapsulation of bacteria gives an enhanced ability for surface attachment, cell-to-cell communication, and genetic exchange. Resistance to antibiotics in biofilms can increase from 10- to 1,000-fold more compared to planktonic bacteria.

Once a pathogen has attached successfully to a site for infection, it must have mechanisms for proliferation. HIV, after going through the steps cited previously, elaborates a conformation-inducing peptide that actuates GP41 like a spring, bringing the virus and lymphocyte membranes into close approximation and permitting the entry of virus RNA into the lymphocyte for subsequent transcription into DNA and integration of the produced DNA into the lymphocyte chromosomes where it can begin to produce new viral components.

Bacteria often secrete enzymes that enhance spread through tissues. The classic example of enzyme secretion and rapid spread through tissues is *Streptococcus pyogenes*. This mechanism is responsible for the fact that the most immediate postoperative surgical site infections, beginning in less than 24 hours from incision, are from *S. pyogenes*. Recently, there has been a radical change in enzyme production by strains of methicillin-resistant *Staphylococcus aureus* (MRSA), with many strains elaborating the Panton-Valentine leukocidin. This leukocidin allows the staphylococcus to spread rapidly through tissue like streptococci, creating an entirely new clinical syndrome for staphylococcal infections. Bacteria may also secrete exotoxins that kill or immobilize cellular host defenses, such as those of *Clostridium perfringens*, the causative agent of gas gangrene. *Streptococcus pneumoniae* and *Haemophilus influenzae* possess capsules that inhibit ingestion by neutrophils or protect them after ingestion into phagocytes. The glycocalyx (slime) that facilitates attachment of certain bacteria to implanted plastic devices is also hydrophobic and interferes with penetration of water-soluble antibiotics to embedded bacteria. Secreted enzymes from some bacteria dissolve tissue proteins to provide nutrients for pathogenic bacteria. Many, if not most, bacteria concentrate iron from the environment, which is an essential factor for enhancing virulence factors for growth and toxin production.

Following local proliferation by a pathogen, elements of virulence favor invasion and dissemination. These can be the same factors that enhance local proliferation, such as capsules, toxins, digestive enzymes, and hydrophobicity. Others include (1) a rigid cell wall, which is a physical barrier to host defenses; (2) cell surface components, other than capsules, that inhibit phagocytosis; (3) the ability to alter its cell surface antigens and thus avoid host-created specific antibodies, such as occurs in influenza A virus and more recently recognized avian influenza human infections; and (4) deterrents to intracellular killing after phagocytosis. Deterrents that have been identified are those that prevent superoxide production by phagocytes that can kill bacteria and mechanisms that avoid fusion of lysosomes within phagocytes, those that contain bactericidal elements, and ingested organisms (e.g., *M. tuberculosis*). (For more information on the organisms described, refer to **72. Clostridium difficile**



**Infection and Pseudomembranous Colitis**, 81 HIV/AIDS, 82 Influenza and Other Respiratory Infections, 93 Staphylococci, 94 Streptococci, and 95 Tuberculosis and Other Mycobacteria.)

## BACTERIAL TOXINS<sup>1</sup>

Bacterial toxins are extensively studied virulence factors. Exotoxins, those secreted by bacteria, particularly Gram-positive bacteria, are often heat inactivated, neutralized by a specific antibody, and may possess enzymatic activity. Possession of potent exotoxins, such as the Panton-Valentine leukocidin of community-associated MRSA (see the preceding section), can considerably enhance the virulence of the staphylococcus. Quantitative increase in toxin production, and production of both toxin A and B, such as in the NAP1/027 (North American PFGE [pulse field gel electrophoresis] type 1 and polymerase chain reaction [PCR], ribotype 027) strain of *C. difficile*, can remarkably enhance virulence. In the case of *C. difficile*, enhanced toxin production has led to creation of an organism that engenders community infection without the need for prior antibiotic treatment of the host to reduce the natural bacterial barrier to the pathogen. Such toxins have sometimes been altered to create effective vaccines, such as diphtheria toxin. Endotoxins are complexes of bacterial proteins, lipids, and polysaccharides that remain firmly within bacteria. They are surface components of Gram-negative bacteria that resist inactivation by heat, are only partially neutralized by antibody, and possess the capability of interacting with host systems to set off cascades of responses that can induce fever, swelling, vascular leaking, pain, and shock, such as the complement cascade, kinins, and cytokine release.

### Types of Bacterial Toxins

Examples of significant bacterial toxins include (1) diphtheria toxin of *Corynebacterium diphtheriae* (toxic to myocardial cells); (2) tetanospasmin of *Clostridium tetani*, which interferes with nerve conduction at the neuromuscular junction; (3) botulinum toxin from *Clostridium botulinum*, which also interferes with neuromuscular transmission; (4) cholera toxin from *Vibrio cholerae*, which increases secretion of fluids into the gastrointestinal (GI) tract, causing profuse diarrhea and fluid and electrolyte loss; (5) enterotoxins of *S. aureus*, which stimulate GI peristalsis, activate complement, and induce shock, as in toxic shock syndrome; (6) *C. difficile* toxins A and B, which create ulcers in the mucosa of the colon; (7) the Panton-Valentine leukocidin of MRSA, which enhances invasion by killing protective neutrophils and enhances rapid spread of infection by digesting subcutaneous proteins; and (8) Gram-negative bacterial endotoxin, which, through its key lipid A moiety, can produce fever, activate blood clotting and fibrinolysis, and inhibit vasoconstriction, causing shock. A variant *E. coli* strain, J5, produces an atypical lipid A that induces antibody when used as a vaccine that is protective against many activities of endotoxin.

## THE CELLULAR IMMUNE SYSTEM<sup>8,9,10,11,12,13</sup>

One limb of the adaptive immune response is called the *cell-mediated immune* (CMI) *system*, which is induced, mediated, or regulated by T-lymphocytes and mononuclear phagocytes. CMI interacts with the antibody-mediated humoral immune system via effects of CD4 T-lymphocytes, B-lymphocytes, and granulocytes. All-important T-lymphocytes are derived from precursors that originate in bone marrow, arising from pluripotential stem cells formed during fetal development, and then migrate to the thymus, hence the designation "T." In the thymus, they further mature as CD4 (helper) lymphocytes and CD8 (cytotoxic) lymphocytes. The former, on being presented with antigen, promote formation of macrophage-stimulating CD4 cells, virus-killing CD8 cells, and memory cells. The latter, when presented with viral antigens, gain the ability to recognize virus-infected cells and adhere to and kill them. These mature CD4 cells then populate bone marrow, spleen, and lymph nodes as the thymus undergoes involution early in life. CMI is highly specific, as is humoral immunity, and is thought to owe its specificity to surface components of T-lymphocytes called *major histocompatibility complexes* (MHCs) (see later).



An enhanced immune response is initiated when a foreign substance, such as a bacterium, virus, or other foreign antigen, is taken up by large phagocytic cells of various types (macrophages in tissues, or Langerhans cells in skin or mucous membranes). These are components of the *innate* immune system. Ingestion of invaders may be sufficient to contain and eliminate an infection. However, if the infection is not contained, the innate system processes the invading organisms and presents the processed antigens to effectors of the *adaptive* immune system. CD4, CD8, (cytotoxic) lymphocytes, and B cells comprise the adaptive immune system. The letter "B" is used to designate that the cells are derived from the bone marrow. The Langerhans cells, having taken up antigens, migrate to lymph nodes where they mature into follicular dendritic cells whose sole function seems to be to present modified antigen to CD4 cells and thus stimulate a vigorous immediate and long-lasting memory immune state. Sometimes B-lymphocytes can directly ingest foreign antigens without prior processing but in general, function best with processed antigen from macrophages and follicular dendritic cells. The initial binding of foreign substances to these phagocytic cells of the innate system occurs to immunoglobulin G (IgG) receptors fixed on the surface of the cells. After the adherent foreign materials are ingested by the phagocytes, they are processed intracellularly to small molecules and then bound to MHCs, genetically coded surface proteins with terminal antigen-binding sites. Larger and smaller microorganisms are processed intracellularly within compartments called *phagosomes*, and their small molecule products are bound to class II MHCs then presented to CD4 lymphocytes. Small microorganisms, principally viruses, are also processed free in cytoplasm of the phagocytic cells, bound to class I MHCs, and presented to CD8 cytotoxic lymphocytes. Transfer of class II MHC-bound materials to CD4 lymphocytes is associated with release of various lymphokines, including interleukin-1 (IL-1), interleukin-6 (IL-6), and, as recently reported, perhaps interleukin-12 (IL-12) and interleukin-16 (IL-16) (see later). If the CMI system is altered, defense against viral, mycobacterial, and fungal infections, among others, can be seriously compromised; antibody production may even be indirectly adversely affected.

T-lymphocytes comprise a number of families that are highly specific in function. All T-lymphocytes are thought to bear the CD3 surface marker. The CD4 marker is on a subset of CD3 cells and identifies a population of helper lymphocytes. Their functions include promotion of phagocytosis of invading pathogens, enhancement of activity of other T- and B-lymphocytes through released lymphokines (cytokines), and preservation of immunological memory, such as occurs with vaccine boosting to induce high-level protective immunity. CD8 cells are another subset of CD3 cells and may be cytotoxic or suppressive in function. Cytotoxic lymphocytes kill cells in which viruses are replicating, and they sometimes kill tumor cells. Suppressor CD8 cells control the intensity of T- and B-lymphocyte activity by suppressing their reproduction and metabolism, thus avoiding an excessively robust response that might be harmful to the host.<sup>14</sup> *Natural killer* (NK) cells, neither CD4 nor CD8 cells, have the ability to lyse and kill tumor cells and virus-infected cells. They bear CD16 and CD56 markers on their surfaces. Certain CD4 lymphocytes are noncommitted ("naive" or "virgin") cells that are not yet specifically antigen committed and thus can respond to novel pathogens and amplify the host's immune response to them.

Cytokines (including lymphokines from lymphocytes) are substances liberated by various cell lines that have specific structures and biological activities. Among them are IL-1, IL-2, IL-4, IL-6, IL-12, IL-16, the interferons (IFNs), lymphotoxin, granulocyte macrophage colony-stimulating factor (GM-CSF), and monocyte colony-stimulating factor. These families of cytokines may possess various physiological properties:

- Priming and stimulating antibody production
- Stimulating reproduction of cell lines (mast cells, eosinophils, macrophages)

- Promoting differentiation of B-lymphocytes or T-lymphocytes, cytotoxic T-lymphocytes, macrophages, and neutrophils
- Fever induction
- Interference with intracellular virus reproduction
- Involution and death of tumor cells
- Protein catabolism
- Inflammation promotion
- Reproduction of granulocytes
- Reproduction of monocytes

## COMPONENTS AND FUNCTION OF THE HUMORAL IMMUNE SYSTEM<sup>15</sup>

In contrast with CMI, humoral immunity is expressed by proteins called *antibodies*. These are found principally within the bloodstream, but secretory antibody is also present in oral secretions, tears, intestinal contents, breast milk, prostate, and, to a small degree, urine. Antibody is also secreted from mucosal surfaces of the female reproductive tract. Antibody is produced by B-lymphocytes, which originate in the fetal liver and bone marrow, then populate the spleen and lymph nodes. In other animal species, B-lymphocytes originate from the bursa of Fabricius, a structure analogous to the human appendix. B-cell numbers are augmented by antigen-stimulated CD4-CD27 cells. For example, in the early stages of HIV infection, CD4-CD27 cells are systematically destroyed, and their complete and permanent elimination in persons who are not treated early in HIV infection or fail to adhere to antiviral therapy leads to a state of rapid immune decline. It is hypothesized that this rapid decline is due to absence of a vigorous humoral immune response to HIV because of the lack of CD4-CD27 cells. B-lymphocytes, stimulated by native or macrophage-processed soluble antigen, divide and mature into antibody-producing cells called *plasma cells* or *plasmacytes*. B-lymphocytes have immunoglobulin M (IgM) receptors on their surfaces, which function in early immune recognition and response, and immunoglobulin D (IgD), which functions in later immune responses. Both classes of surface antibodies are specific to individual foreign antigens.

All antibody molecules possess multiple structural sites referred to as *Fab* (fragment, antigen-binding), which react with specific antigens, and one other structural site called *Fc* (fragment, crystallizable), which distinguishes among the antibody classes (Figure 22-1).

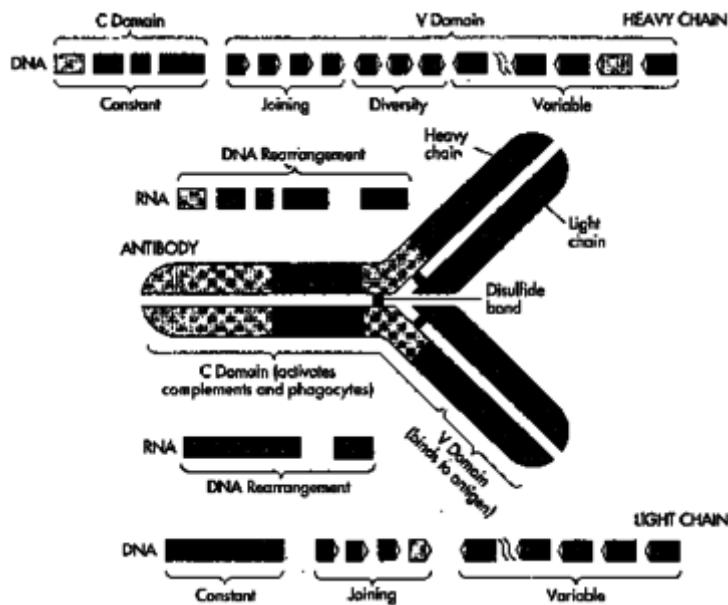
### Figure 22-1.

Antibody molecule is made up of a pair of heavy chains and a pair of light chains. The chains are encoded by genes that consist of different DNA segments. These segments rearrange to make genes for chains that are different in each B cell. The joining is variable, so only a few gene segments generate the estimated 100 million antibodies the body is capable of producing. (From Nossal JV. Life, death and the immune system. *Sci Am* 1993;269:55.)

[View Image](#)



Immunoglobulin G (IgG) is the major circulating and extravascular (interstitial) antibody—a protein molecule of approximately 160,000 molecular weight that possesses two Fab reactive sites linked to one Fc component. IgG is the late-occurring immunoglobulin in an immune response and is the longest lived. Because IgG enters interstitial tissue relatively easily, it is the major antibody to protect "tissue." There are four subclasses: IgG1 to IgG4. IgM consists of five limbs, each containing two Fab sites, all linked to an Fc molecule. Thus, an intact IgM molecule has 10 reactive Fab sites. IgM is the first reacting immunoglobulin in an adaptive immune response to an infection and is generally produced for



no more than 6 months after the onset of the infection. Exceptions include antibody to polysaccharides, which are IgM and long-lived, and antibody to blood group substances in the ABO blood group system. Because of its very large molecular weight, IgM is largely contained within the vascular tree.

Immunoglobulin A (IgA) is the principal secretory antibody in humans, primarily produced in plasma cells residing in mucous membranes, and commonly secreted as a dimer of two IgA molecules, each with two Fab fragments and one Fc, and linked together to T-piece (secretory protein). Smaller quantities of IgA, as monomers and without T-piece, circulate in the bloodstream. When IgA reacts with

antigen, it may cause the release of histamine from mast cells and basophilic neutrophils, leading to an allergic clinical response.

Immunoglobulin D (IgD) is an immunoglobulin of characteristic structure with two Fab sites and one Fc piece, which is present principally on the surface of lymphocytes, where it serves to bind specific antigens. Trace amounts circulate free in plasma.

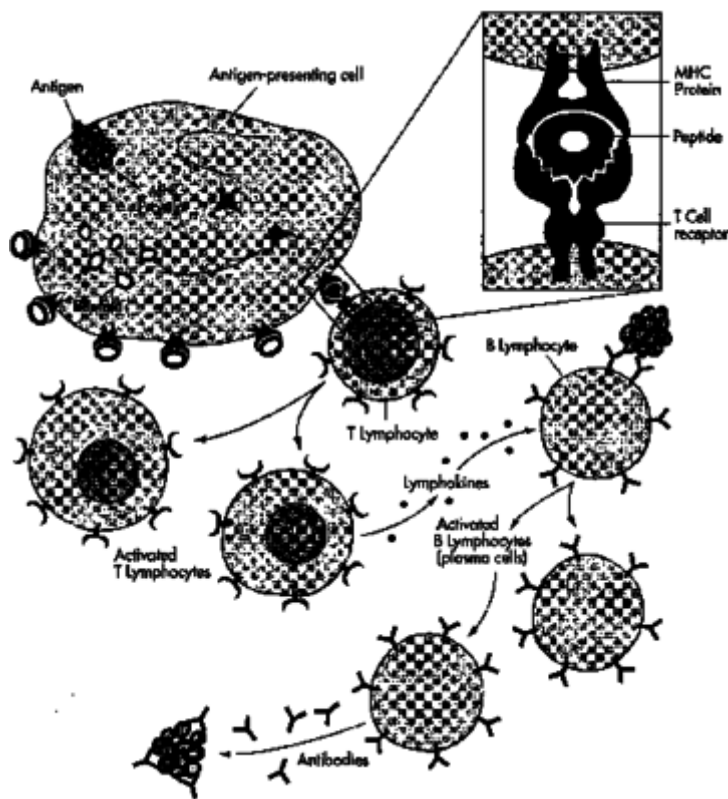
Immunoglobulin E (IgE) is the principal allergy-inducing immunoglobulin, known as *reagin*. It consists of two Fab fragments linked to an Fc piece, and, when it reacts with antigen, stimulates release of histamine and other inflammatory substances from basophils and mast cells. IgE-producing plasma cells are found in large numbers on the mucous membranes of individuals with significant seasonal allergies. Its activity in the GI tract may aid in protection against intestinal parasites.

The functions of immunoglobulins relate to events subsequent to their binding to their respective specific antigens. When two molecules of IgG bind to an antigen, such as a bacterium, they activate the complement system and thus facilitate phagocytosis, intracellular killing of pathogens, and lysis of cells and bacteria. A single molecule of IgM, presumably because of its numerous reactive Fab sites, can activate complement when it reacts with its antigen. IgA binds to organisms attempting to invade mucous membranes, interfering with motility of the organisms, adhesion to the membrane, and promoting phagocytosis. IgA is highly effective in preventing virus infections of the respiratory and intestinal mucosa, such as rhinovirus, influenza virus, coronavirus, and enteroviruses (e.g., poliovirus and Coxsackie virus). It is also thought to be a key protector against intestinal parasites. Functions of IgD and IgE were previously described. Figure 22-2 presents a summary of defense against infection provided by the immune system.

## NONSPECIFIC HOST DEFENSES<sup>16,17,18</sup>

The human host possesses a range of naturally occurring obstacles to invasion by a broad range of potentially pathogenic organisms. Caucasians and Africans possess vigorous natural resistance to deep mycoses, including *Histoplasma capsulatum* and *Coccidioides immitis* and to rubeola virus, whereas Asians lack resistance to the former two and Alaskan and Hawaiian natives to the latter. Successive epidemics of fatal rubeola swept both Alaska and Hawaii after introduction by European colonists. Skin and mucous membranes are important mechanical barriers to infection. The normal flora deplete the

environment of nutrients essential for pathogens, compete for tissue-binding sites, and secrete naturally occurring antibiotics that kill potential pathogens. Skin secretes short-chain fatty acids lethal for many pathogens.



**Figure 22-2.**

How the immune system defends the body. The body is protected by a diverse army of cells and molecules that work in concert. The ultimate target of all immune responses is an antigen, which is usually a foreign molecule from a bacterium or other invader. Specialized antigen-presenting cells, such as macrophages, roam the body, ingesting the antigens they find and fragmenting them into antigenic peptides. Pieces of these peptides are joined to major histocompatibility complex (MHC) molecules and are displayed on the surface of the cell. Other white blood cells, called T-lymphocytes, have receptor molecules that enable each of them to recognize a different peptide-MHC combination. T cells activated by that recognition divide and secrete lymphokines, or chemical signals, that mobilize other components of the immune system. One set of cells that responds to those signals comprises the T-lymphocytes, which also

have receptor molecules of a single specificity on their surface. Unlike the receptors of T cells, however, those of B cells can recognize parts of antigens free in solution without MHC molecules. When activated, the B cells divide and differentiate into plasma cells that secrete antibody proteins, which are soluble forms of their receptors. By binding to antigens they find, the antibodies can neutralize them or precipitate their destruction by complement enzymes or by scavenging cells. Some T and B cells become memory cells that persist in the circulation and boost the immune system's readiness to eliminate the same antigen if it presents itself in the future. Because the genes for antibodies in B cells mutate frequently, the antibody response improves after repeated immunizations. (From Janeway CA. How the immune system recognizes invaders. *Sci Am*1993;269:75.)

[View Image](#)



Host physiology may help prevent infection. Fever, naturally regulated in the hypothalamus, may be beneficial to the host. Fever is induced through the hypothalamus by endogenous pyrogenic substances. IL-1, IL-2, IL-6, IL-8, tumor necrosis factor (TNF), IFNs, and colony-stimulating factors all affect the thermoregulatory center in the hypothalamus. Likewise, endogenous antipyretics prevent dangerously high fevers. These include arginine vasopressin, melanocyte-stimulating hormone, and TNF. Whether fever is beneficial or harmful to the host continues to be debated, despite years of research attesting to probable benefit.<sup>18,19,20,21,22</sup> Phylogenetic studies indicate that fever is an evolutionally determined

protective mechanism. Animals lacking the ability to generate fevers naturally seek warmer environs in the face of infections, and when they are prevented from doing so, they have higher mortality than permitted cohorts. In vitro studies indicate that many host defenses are more efficient against pathogens at higher physiological temperatures. Some organisms, such as *Cryptococcus*, will not grow above 38°C. Conversely, certain responses to fever may be deleterious. Febrile convulsions, frequently triggered by reactivation of latent herpes virus 6 in the central nervous system (CNS) by fever, are one

example of a possible adverse effect of fever.<sup>17</sup> Persons with underlying heart disease and reduced stroke volume may develop worsening congestive heart failure (CHF) in the face of tachycardia induced by fever. It is probably safe to generalize that a low-grade fever, between 38°C and 38.5°C, enhances natural defenses. Higher body temperature in individuals with cardiovascular disease or history of febrile convulsion should be considered for treatment.

Secretions, especially from mucous membranes, help protect against infection, through antibacterial contents and promotion of flow. Lysozyme is a low-activity enzyme secreted by mucous membranes and kills a narrow range of Gram-positive bacteria. Gastric acid is a major barrier to infection of the intestinal tract with swallowed pathogens. Antacids or acid secretion blockade markedly increases the susceptibility of experimental animals to intestinal pathogens. New evidence, for example, suggests that routine use of gastric acid inhibition preoperatively may actually increase susceptibility to postoperative infection. Some secreted enzymes from salivary glands, the pancreas, and intestinal mucosal cells partially digest invading pathogens. Bile salts are inhibitory to a range of pathogenic bacteria. The addition of ciliary sweeping, which is both unidirectional and coordinated, to secretions helps wash the nose, mouth, respiratory tract, and pharynx of bacteria, which are then swallowed and inactivated by gastric acid. Motility in the alimentary and urinary tracts expels many invading pathogens and toxic substances.

The vascular tree contains circulating defenses that are naturally occurring (components of innate immunity). Natural antibody, formed in response to normal flora, cross-reacts with pathogens and helps expel them. Fibronectin is a circulating protein that binds to pathogen receptors and prevents their adherence to cells. Hormones, such as estrogens, control secretions and characteristics of mucous membrane cells and thus the nature of bacteria inhabiting their surfaces. Circulating phagocytic neutrophils and monocytes, without aid of humoral elements, can ingest and kill many pathogens (see preceding description of *innate* immunity).

## COMPONENTS AND ACTIVITIES OF THE COMPLEMENT SYSTEM<sup>23,24</sup>

The complement system consists of eleven sequentially reacting serum proteins that, in their activated forms, possess biological activities essential to host defenses against many invading microorganisms and tumor cells.

Activation of the complement system may occur in either the classical or alternate pathway. When antigens, including pathogenic organisms, interact with IgG or IgM antibody, they activate complement in the classical pathway. Certain microorganisms spontaneously activate the alternate pathway. The net effect of activation through either pathway is enhancement of phagocytosis, increase in vascular permeability, blood vessel dilatation, chemoattraction of neutrophils into an area of inflammation, smooth muscle contraction, and lysis of certain pathogens, especially the *Neisseriaceae* family, by the terminal components.

The components of the human complement system include C1q, r, and s; C4; C2; C3; C5; C6; C7; C8; and C9. This is also the sequence of activation in the classical pathway. The alternate pathway begins with direct activation of C3, without the necessity of activation of the C1 complex, C4, or C2 (Figure 22-3). In the process of alternate pathway activation, a fragment of C3, termed C3b, is created, which generates a positive feedback loop to amplify complement activation.

To enhance destruction of foreign cells while protecting host cells, the host cells possess complement regulatory proteins that block complement activation on their surfaces, which could be destructive. Alternatively, foreign cells possess on their surfaces components not present on host cells, which



facilitate complement activation. These components are essential for complement to distinguish between host and foreign cells.

Some rare individuals are genetically deficient in certain complement components. These may result in congenital illnesses, such as angioneurotic edema associated with deficiency of C1, recurrent bacterial infections in those deficient in C2 or C3, and recurrent bacteremia with pathogenic *Neisseria* in individuals deficient in C7, C8, or C9. These naturally occurring deficiencies have helped define the roles of complement in natural resistance and host homeostasis.

## THE PHAGOCYtic CELL SYSTEM<sup>25,26</sup>

Several cell lines comprise the phagocytic *innate* cell system. Granulocytes (polymorphonuclear [PMN] leukocytes or "polys") consist of three classes: neutrophils, eosinophils, and basophils. Mononuclear phagocytes occur as circulating monocytes and tissue fixed macrophages. The latter occur in the liver as Kupffer cells, the lung as alveolar macrophages, in the spleen as histiocytes, and in the CNS as dendroglia. Langerhans cells, in skin and mucous membranes, are phagocytic cells that mature in lymph nodes, marrow, or spleen into follicular dendritic cells.

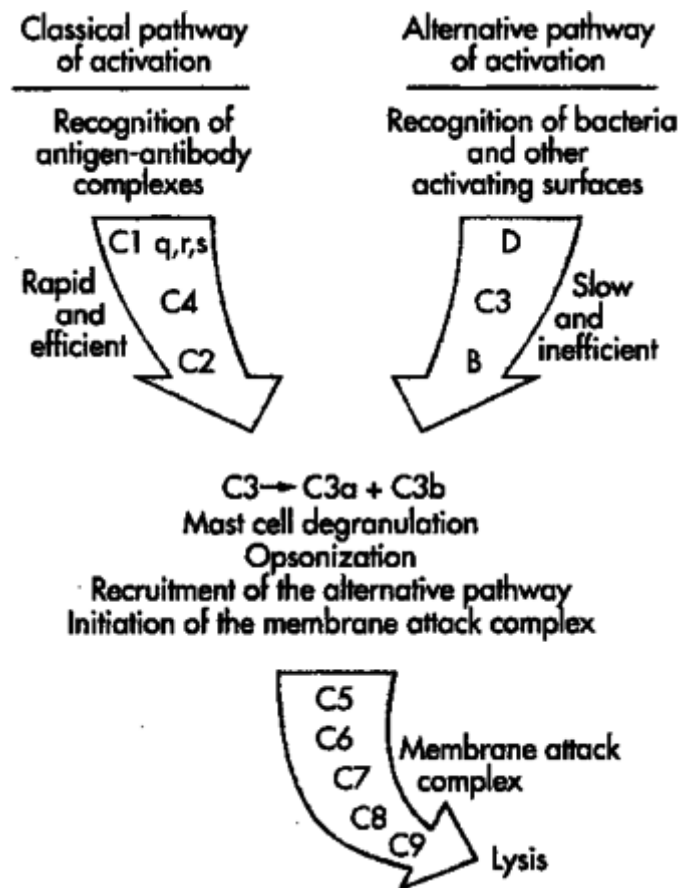


Figure 22-3.

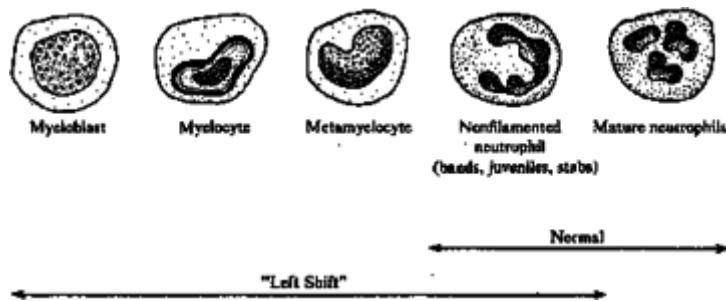
The complement system. The complement system consists of three families of proteins. Two of these, the classical pathway of activation and the alternative pathway of activation, cause the cleavage of C3 into two fragments, C3b and C3a. These fragments have important biologic activities. In addition, C3b, together with elements of the classical pathway (Bb, properdin), forms enzymes (C5 convertases) that cleave C5, the initial member of the terminal family of proteins. Cleavage of C5 leads to the formation of the membrane attack complex that can result in osmotic lysis of cells. (From Paul WE. *Fundamental Immunology*. New York: Raven, 1993.)

[View Image](#)



Granulocytes have inclusions (granules) within their cytoplasm that are recognized by their staining properties in the laboratory and that give the three classes their names. These granules contain elements that may be released into the surrounding location of an infection or intracellularly into a phagosome to degrade and kill invading pathogens. Neutrophils are the principal antibacterial PMNs and

the first cells to arrive at the site of an inflammatory focus. Basophils, which have no defined role in resistance to infection, are related to mast cells, contain large quantities of histamine, and participate in allergic responses. Eosinophils are important in hypersensitivity reactions and defense against parasites and are early arrivals at the site of a primary exposure to an antigenic substance. See Figures 22-3 and 22-4 for stages of neutrophil development. Note that left-to-right orientation (immature cells to the left) has given rise to the common but often misused term "left shift" in clinical jargon. In reality it implies an abundance of immature neutrophils (e.g., increased "band" forms of PMNs) in the peripheral blood.

**Figure 22-4.**

A laboratory finding of increased numbers of immature neutrophils in the peripheral blood is referred to as a "left shift."

[View Image](#)



neutrophils. They provide major defense against intracellular pathogens, such as *Brucella*, *Toxoplasma*, and *Trypanosoma cruzi*. They also function as antigen-processing and -presenting cells for induction of the immune response (see previous text) and ingest and dispose of effete, damaged, or nonfunctioning host cells. They help in the process of tissue repair and lessen the cellular response that occurs in inflammation.

Mononuclear phagocytes (circulating and fixed) are effector cells in inflammation, arriving after

## NEUTROPHILS: OPSONIZATION AND PHAGOCYTOSIS<sup>1,2,3,4,5,6,7</sup>

Neutrophils function through migration, opsonization, phagocytosis, and intracellular killing. Migration is directed into a site of infection by chemical concentration gradients of microbial elaborated substances or activated complement components. Opsonization occurs when antibody and complement coat a pathogen. Their presence on the surface of the pathogen promotes phagocytosis, the attachment and engulfment of a microbe, and enclosure of it within a vacuole (phagosome). Phagocytosis initiates a burst of neutrophil metabolism, resulting in generation of hydrogen peroxide and superoxides, which are microbicidal when released into phagosomes. Release of microbicidal and digestive materials from lysosomes of neutrophils into phagosomes is enhanced by opsonization. Granule contents released into the extracellular environment function as attractants for more neutrophils. The normal number of white blood cells (WBCs; collectively includes the five cell lines of leukocytes previously described—neutrophils, eosinophils, basophils, lymphocytes, and monocytes) in peripheral blood is between 4,000 and 10,000 cells/mm<sup>3</sup>. WBC numbers in excess of 10,000 are termed *leukocytosis*, whereas WBC counts less than 4,000 are called *eukopenia*. If the absolute number of neutrophils falls below 1,000 cells/mm<sup>3</sup> or resides below 500, there is significant danger of fatal infection. Absolute neutrophil count is derived by multiplying the cumulative percent of mature and immature PMNs times the total WBC count.

## Conclusions

Infection results when an imbalance occurs between the mechanisms that microorganisms employ to induce infection and the complex physiological response systems that are employed by a host to prevent such infections. Infection preventionists must understand these mechanisms in order to design and implement effective infection prevention and control programs.

## Supplemental Resources

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# The Immunocompromised Host

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## Abstract

*Infectious diseases cause significant morbidity and mortality in immunocompromised patients. The timing and specific type of infection is often predictable and may be preventable. This chapter provides a practical overview of the broad topic of the immunocompromised host and prevention of infection, focusing on specific types of immune compromise and the types of infection associated with them. Methods of augmenting host resistance are discussed, as well as techniques to avoid exposure to potential pathogens. Topics have been chosen to include areas of care that differ from those of the immune competent patient, including isolation precautions, immunizations, augmentation of host resistance, and antimicrobial prophylaxis. National practice guidelines are cited, when available, and, where no consensus exists, practical recommendations based on available literature are provided. A systematic approach to care of the immunocompromised host, tailored to the needs of each individual patient, will reduce the risk of infection.*

## Key Concepts

- Several categories of immune compromise exist, and some patients may have more than one type.
- Thorough history taking and detailed physical examination often reveal potential problems.
- Host resistance to infection can often be augmented.
- Avoidance of hospitalization is desirable, whenever feasible.
- Consistent use of standard precautions, specifically hand hygiene and respiratory etiquette as well as transmission-based precautions when indicated, is the most important of all interventions.

## Background

The immunocompromised host is a person with impairments in the body's normal mechanisms of defense against infection. A review of normal host defenses is beyond the scope of this chapter, but references to recent discussions of the topic can be found in the Supplemental Resources. Several categories of host abnormality that are commonly associated with impaired resistance exist. Within these broad categories, variations in immunologic function are recognized. The degree of impairment may wax or wane with time and therapy. Comprehensive management of the immunocompromised host entails all of the following elements: (1) recognition of the categories of host defects that are associated with impaired resistance, (2) knowledge of the type of infection to anticipate in each category of immune compromise, (3) the most common portals of entry for opportunistic organisms, (4) the fact that clinical manifestations of illness may be different in the immunocompromised host, and (5) an understanding of the broad array of modalities for prevention of infection.

## Basic Principles

### RECOGNITION AND CHARACTERIZATION OF THE IMMUNOCOMPROMISED HOST

The immunocompromised host is an individual who has one or more defects in the body's normal defense mechanisms that predisposes him or her to infections, often life threatening, that would otherwise not occur. These individuals continue to be at risk for common infections as well, but these may pursue a more aggressive course than they might otherwise. The number and type of immunocompromised hosts are constantly increasing for several reasons, including the aging of the U.S. population, medical advances that have kept persons alive who previously would have died of their underlying disease, pandemic infection by human immunodeficiency virus (HIV), Hepatitis B (HBV) and Hepatitis C (HCV) viruses, homelessness and the resultant lack of basic hygiene and good nutrition, the obesity epidemic, tobacco and recreational drug abuse, diminishing access to primary care with resultant late diagnosis of diseases, and immigration of persons from developing parts of the world where exotic and potentially immunocompromising infectious agents are endemic.

The categories of host defects that are commonly associated with impaired resistance are listed in Table 23-1.

Within these categories, broad variations in immunological function are recognized. Most patients have abnormalities that may wax or wane with time and therapy. For this reason, the individual patient's risk of infection is best evaluated by defining his or her net state of immunosuppression.<sup>1</sup>

Table 23-1. Categories of Host Defect That Are Associated With Impaired Resistance

- I. Defects in the cutaneous barrier to invasion of endogenous or acquired organisms
  - A. Surgical incisions
  - B. Thermal or chemical burns
  - C. Traumatic injuries to the skin
  - D. Severe dermatologic conditions

1. Poorly controlled eczema or psoriasis
2. Scleroderma
3. Mycosis fungoides
4. Chronic fungal infections of the skin or nail beds
- E. Indwelling intravenous lines, either temporary or long term
- F. Injections, either legal/medicinal or illicit
- G. Ulcers: decubitus, diabetic, vascular insufficiency, others
- II. Mucous membrane barrier defects
  - A. Mucositis induced by irradiation or chemotherapy
  - B. Trauma to the head and neck
  - C. Smoking (tobacco, recreational drugs)
  - D. Inhalation injuries (heat, smoke, caustic chemicals, recreational drugs)
  - E. Poor oral hygiene
  - F. Erosions from nasogastric or endotracheal tubes or indwelling Foley catheters
  - G. Antacids, proton pump inhibitors, etc.
1. Decrease the number of ingested organisms necessary to cause gastrointestinal disease, including *Clostridium difficile*
2. Allow a reservoir of bacteria to develop in the stomach, which can be regurgitated and aspirated
- III. Conditions that cause obstruction of a natural body passage
  - A. Tumors of the lung, gastrointestinal tract, pancreatic head, elsewhere
  - B. Foreign bodies: aspiration, endotracheal tubes
  - C. Renal stones, gallstones
  - D. Prostatic enlargement
  - E. Cystic fibrosis
- IV. Abnormal number or function of granulocytes
  - A. Leukemia
  - B. Chemotherapy for malignant disease
  - C. Aplastic anemia
  - D. Granulocytopenia as an adverse drug reaction

## E. Dysfunctional granulocytes despite normal numbers

1. Diabetes mellitus, especially if poorly controlled
2. Corticosteroid administration
3. Rheumatoid arthritis
4. Renal failure
5. Congenital disorders of phagocyte function: Chediak-Higashi syndrome, chronic granulomatous disease, hypereosinophilic (Job) syndrome, others

## V. Abnormalities of cell-mediated immunity

- A. Bone marrow transplantation
- B. Human immunodeficiency virus (HIV) infection
- C. Chemotherapy for malignancy
- D. Tumor necrosis factor inhibitors for rheumatologic disorders and Crohn's disease
- E. Aging
- F. Hodgkin's disease, non-Hodgkin's lymphoma
- G. Corticosteroid administration
- H. Third trimester of pregnancy
- I. Severe malnutrition

## VI. Abnormalities of humoral immunity

- A. Bone marrow transplantation
- B. HIV infection
- C. Chronic lymphocytic leukemia
- D. Multiple myeloma and Waldenström's macroglobulinemia
- E. Aging
- F. Childhood immunoglobulin deficiencies
- G. Acquired hypogammaglobulinemia (common variable immunodeficiency)

## VII. Patients with defects in multiple arms of immunity

- A. Aging
- B. Severe trauma
- C. Alcoholism, chemical dependency



D. Malnutrition

E. Obesity

F. Splenectomy

G. Organ failure (cirrhosis, chronic renal failure with or without hemodialysis)

H. Spinal cord injury

I. High-dose corticosteroid administration

J. Chemotherapy

The net state of immunosuppression is determined by the interaction of several variables, including: (1) host-defense defects caused by the disease process itself; (2) the type of immunologic abnormality induced by a specific agent; (3) the dose, duration, and temporal sequence of immunosuppressive therapy; (4) the presence or absence of neutropenia and/or lymphopenia; (5) the state of humoral and cellular host defenses; (6) the integrity of the skin (to include presence or absence of an indwelling intravenous catheter) and mucosal surfaces of the body; (7) metabolic factors, such as malnutrition, uremia, hyperglycemia, and hepatic dysfunction; (8) abnormalities of the reticuloendothelial system, most notably the absence of splenic function; and (9) the presence or absence of immunomodulating infections, such as HIV, hepatitis viruses, cytomegalovirus (CMV), Epstein-Barr virus (EBV), and human herpesvirus 6 (HHV-6).<sup>1,2,3</sup> Additional stressors include smoking,<sup>4</sup> injection drug use,<sup>5</sup> obesity,<sup>6</sup> and alcoholism.<sup>7,8</sup> The net state of immunosuppression not only determines the risk of infection, the type of infection to be anticipated, and the need for prevention, but it also influences the degree of effectiveness of intervention attempts.

## Opportunistic Organisms That Most Often Cause Disease in the Immunocompromised Host

In the immune-intact individual, only a relative handful of pathogens are able to cause disease. These have been called "true pathogens" and include, for example, such "classic" organisms as influenza, *Salmonella typhi*, *Yersinia pestis*, *Bacillus anthracis*, and *Corynebacterium diphtheriae*. Certain exotic diseases, such as the hemorrhagic fever viruses, fall into this category as well.<sup>9</sup> As the host becomes progressively more immunocompromised, progressively less virulent organisms are able to become pathogenic. Thus, patients with major immune defects are subject to a larger number and greater variety of infectious diseases. A recent survey identified 1,407 currently recognized species of human pathogen, many of which have been described only recently.<sup>10</sup> It can be anticipated that this list will continue to grow as the result of such forces as population growth, climate change, habitat destruction, or encroachment on wilderness habitats that are reservoirs for animals that harbor novel infectious agents.<sup>11</sup>

Although the classic pathogens also cause disease in the immunocompromised host, often their presentation is different than would be seen in the healthy individual.

Table 23-2 lists the organisms that are commonly considered opportunistic in the setting of different types of immune compromise.

## Opportunistic Organisms Encountered Internationally

An increasing number of individuals who were born in the developing world now reside in the United States. A variety of organisms that are uncommon in the United States are endemic in developing countries and may be associated with worsening chronic disease or reactivation in the setting of immunosuppression.<sup>12,13</sup>

Table 23-2. The Most Common Opportunistic Infections Associated With Specific Immune Deficits

I. Breaks in cutaneous integrity: invasion by skin flora

- A. *Staphylococcus aureus*, coagulase-negative species of *Staphylococcus*
- B. *Streptococcus pyogenes* (group A beta-hemolytic *Streptococcus*)
- C. *Corynebacterium* spp. (aka "diphtheroids")
- D. *Malassezia furfur*, if lipid-containing intravenous infusions are being given

II. Defects in mucous membranes, with invasion by resident flora

- A. Anaerobic bacteria (*Bacteroides fragilis*, *Clostridium perfringens*, *C. septicum*)
- B. Aerobic Gram-negative bacilli
- C. *Candida* spp. and *Torulopsis glabrata*
- D. *Enterococcus* spp. and *Streptococcus bovis*

III. Obstruction of a natural body passage: overgrowth or invasion (or both) by resident flora

- A. Lung: oral flora; if patient is hospitalized, nosocomial Gram negatives, *Staphylococcus aureus*, including methicillin-resistant *S. aureus*
- B. Biliary and pancreatic system: aerobic Gram-negative bacilli, *Enterococcus*, anaerobes
- C. Colon: aerobic Gram-negative bacilli, anaerobes, *Streptococcus bovis*

IV. Granulocytopenia (defined as absolute neutrophil count <500/mL)

- A. Duration of 2 weeks or less: aerobic Gram-negative bacilli, *S. aureus*, and coagulase-negative *Staphylococci*
- B. Duration of more than 2 weeks: the above plus *Candida* spp., *T. glabrata*, *Aspergillus* spp.

V. Dysfunction of cell-mediated immunity

A. Bacteria: primarily intracellular pathogens

- 1. *Listeria monocytogenes*
- 2. *Salmonella* spp.
- 3. *Mycobacterium* spp., including *M. tuberculosis*
- 4. *Nocardia* (*N. asteroides*, others)
- 5. *Legionella pneumophila*, other species of *Legionella*

6. *Rhodococcus equi*

7. *Pseudomonas pseudomallei*

B. Fungi

1. *Cryptococcus neoformans*

2. *Candida* spp. and *T. glabrata*

3. *Coccidioides immitis*

4. *Histoplasma capsulatum*

5. *Penicillium marneffei*

6. *Pneumocystis jiroveci*

C. Viruses

1. Herpes group, especially cytomegalovirus, herpes zoster

D. Protozoa

1. *Toxoplasma gondii*

2. *Cryptosporidium* spp. (*C. parvum*, others)

E. Helminths

1. *Strongyloides stercoralis*

VI. Splenectomy or humoral dysfunction-encapsulated bacteria

A. *Streptococcus pneumoniae*

B. Encapsulated strains (especially type B) of *Haemophilus influenzae*

C. *Neisseria meningitidis*

***Internationally Acquired Infections That May Go Unrecognized for Prolonged Periods***

• *Strongyloides stercoralis*

• Trematodes such as *Schistosoma* spp., *Fasciola*, *Opisthorchis*, *Clonorchis*, *Paragonimus*

• *Pseudomonas pseudomallei*

• Hydatid disease (*Echinococcus* spp.)

• *Trichinella spiralis*

• Tapeworms, especially *Taenia solium*

• Nematodes (*Onchocerca volvulus*)

• HTLV-1/2

- *Trypanosoma cruzi* (Chagas disease)

#### Table 23-3. Sources of Opportunistic Infection

##### I. Opportunists that are more commonly (but not exclusively) endogenous

- A. *Mycobacterium tuberculosis* (lung, lymphatics, others)
- B. Coagulase-negative *Staphylococci* (skin)
- C. *Corynebacterium* spp. (skin)
- D. *Enterococcus* spp. and *Streptococcus bovis* (gastrointestinal tract)
- E. *Clostridium septicum* (gastrointestinal tract)
- F. *Candida* spp. and *Torulopsis glabrata* (oropharynx and gastrointestinal tract)
- G. *Coccidioides immitis* (lung, liver, spleen, others)
- H. *Histoplasma capsulatum* (lung, liver, spleen, others)
- I. *Malassezia furfur* (skin)
- J. *Pneumocystis jiroveci* (lungs, rarely elsewhere)
- K. *Toxoplasma gondii* (central nervous system)

##### L. Herpes simplex and herpes zoster (skin and mucous membranes)

##### II. Opportunists that are more commonly (but not exclusively) exogenous

- A. *Clostridium difficile* (hands of personnel, fomites)
- B. *Legionella pneumophila* (tap water and air conditioning systems, spread by aerosols)
- C. *Rhodococcus equi* (soil)
- D. *Aspergillus* spp. (ventilation systems, especially during construction or demolition)
- E. Zygomycetes (ubiquitous in the environment)
- F. Rapidly growing mycobacteria such as *M. fortuitum*, *M. chelonae* (environmental sources)
- G. *Cryptosporidium* (water supplies)
- H. Viruses other than herpes group (hands, droplet nuclei, fomites occasionally)

##### III. Opportunists that can be either endogenous or exogenous

##### A. Aerobic Gram-negative bacilli

1. Endogenous from oropharynx and gastrointestinal tract
2. Exogenous from aerosols, contaminated food, fomites

##### B. *Staphylococcus aureus*

1. Endogenous as resident skin flora, nasal carriage
2. Exogenous from hands of personnel

### ***The Source of the Infection May Be Endogenous, Exogenous, or Both***

Isolation of a specific microorganism may at times allow its source of origin, either endogenous or exogenous, to be deduced (Table 23-3). This is helpful in determining the optimal way to proceed with individual patients. Note that organisms that arise from an endogenous source in one patient may then be transmissible to healthcare personnel or patients.

### ***Most Important Portals of Entry for Opportunistic Organisms***

#### SKIN

The skin is an important portal, especially for individuals with long-term venous access devices and patients with major defects in skin integrity, such as burns. In one recent review of the microbiology of burn wounds *Staphylococcus aureus* and *Pseudomonas aeruginosa* were the two dominant organisms, representing 23 percent and 19 percent of all isolates from burn wounds, respectively. The majority of the remainder of isolates fell into seven genera (Table 23-4).<sup>14</sup> However, microbiologic patterns differ

among institutions and evolve over time. Mehta et al.<sup>15</sup> found diminishing importance of *P.*

*aeruginosa* and *S. aureus* in comparison of isolates from 1997 to 2002 and from 2002 to 2005, with increasing prevalence of *Acinetobacter*, *Klebsiella*, and other Gram-negative rods. *Enterococcus* may play a role in some centers.<sup>16</sup> Thus, in choosing empiric antibiotic regimens it is important to review the

recent patterns from an individual institution. Finally, the emergence of methicillin resistance among *S. aureus* (MRSA) has become a major concern for all institutions.<sup>17,18</sup>

**Table 23-1** Bacteria and Fungi That Constituted 1,830 Isolates Recovered From 1,234 Burn Wound Infections: NNIS System, CDC, 1980–1998

Pathogen	Number of Isolates (%)
<i>Staphylococcus aureus</i>	420 (23)
<i>Pseudomonas aeruginosa</i>	353 (19.3)
<i>Enterococcus</i> spp.	202 (11)
<i>Enterobacter</i> spp.	176 (9.6)
<i>Escherichia coli</i>	131 (7.2)
Coagulase-negative staphylococci	78 (4.3)
<i>Candida albicans</i>	64 (3.5)
<i>Serratia marcescens</i>	64 (3.5)
<i>Klebsiella pneumoniae</i>	48 (2.6)
Others	294 (16)

#### OROPHARYNX

Hospitalization is associated with acquisition of healthcare-associated organisms within the oropharynx that replace the normal flora.<sup>19,20</sup> The presence of a nasogastric tube changes the ecosystem of the oropharynx, with increased prevalence of *P. aeruginosa*.<sup>21</sup> Nasotracheal or orotracheal intubation also predisposes to colonization with healthcare-associated organisms and leads to healthcare-associated pneumonia due to blockage of sinus drainage, mechanical trauma to the mucosa, impaired swallowing of secretions, adherence of bacteria to a foreign body, pooling of secretions around the cuff, mucosal ischemia around the cuff, and impaired ciliary clearance and cough.<sup>22</sup> From the oropharynx affected by chemotherapy, thermal burn, or radiation, local invasion into the bloodstream can occur by the members of the normal oropharyngeal flora (Table 23-3) or healthcare-associated organisms.

## LUNG

The lung is the common portal of entry for *Mycobacterium tuberculosis*, *Aspergillus* spp., and regionally important fungi, such as *Coccidioides immitis*, *Histoplasma capsulatum*, *Penicillium marneffe*, and *Paracoccidioides brasiliensis*. Within the gastrointestinal tract, due to decreased acid production, use of enteral feeding, and stress ulcer prophylaxis, the stomach becomes colonized with bacteria, particularly Gram negatives.<sup>23</sup> The contribution of this site as a potential source of healthcare-associated pneumonia continues to be a topic of debate with studies demonstrating from no role to up to 15 percent of patients with pneumonia having the stomach as the source of pneumonia.<sup>23</sup>

## GASTROINTESTINAL TRACT

In the neutropenic host, the gastrointestinal tract is the most important source for bacteremia as the result of transmigration across the mucosal barrier.<sup>24</sup>

### ***Clinical Manifestations of Disease May Be Different in the Immunocompromised Host Versus the Intact Host***

The immunocompromised host may present with a very different clinical picture than the intact host. The pace of disease may be much more rapid. This is especially true in the asplenic patient presenting with bacterial infection and the neutropenic patient. Seemingly trivial problems may rapidly become life threatening. Neutropenic patients have little purulence at the site of infection and less obvious chest radiographic findings. Elderly patients may have confusion or incontinence as their only manifestation of infection. Patients receiving corticosteroids may have diminished or absent fever response. Patients who are sedated or have central nervous system dysfunction perceive pain less well and are less able to articulate a problem to the examiner. Finally, the white blood cell count may be in the normal or even low range but demonstrate an increased number of immature (band) forms.

## Preventing Infection in the Immunocompromised Host

### **IDENTIFY AND ADDRESS SPECIFIC PROBLEMS BEFORE THE PATIENT IS SUBJECTED TO IMMUNOCOMPROMISING PROCEDURES**

A thorough history and a detailed physical examination are essential in the care of the immunocompromised patient. Potential problems can be identified in a careful interview, which may be supplemented with a printed questionnaire for consistency.

The patient may provide information about previous infections that imply specific types of immune dysfunction (Table 23-2).

A complete listing of all medications should include all over-the-counter medications. In addition, patients may seek dual services with traditional as well as alternative healthcare providers and may be taking substances in the forms of teas, food additives, or pills that, although "natural," may still affect the immune system.<sup>25,26</sup> These substances should also be noted on the intake form.

Birthplace and geographical areas of residence or extensive travel are important clues to potential latent infections. Pet ownership, hobbies, and recreational activities such as spelunking, hiking and camping, and hunting or fishing may expose the patient to zoonotic infections. The patient's sexual history should be obtained, including the incidence of sexually transmitted infections and their treatments, as well as the history of drug use, including quantity of alcohol consumption; oral, inhaled, or injectable illicit substances; and misuse of prescription drugs. Finally, a meticulous systems review and physical examination should be performed.

Routine lab work should include a complete blood count with differential, a chemistry panel that includes a measurement of liver enzymes, renal function, and electrolytes. Nutritional status can be assessed by calculation of the body mass index (weight in kilograms/square of the height in meters) along with serum albumin, transferrin, and total lymphocyte count.

Patients requiring long-term venous access should have such devices placed well in advance of any immunosuppressive therapy. Central venous access should be obtained using sterile technique, including donning of masks, gowns, sterile gloves, and the use of a sterile drape. Detailed recommendations regarding strategies to prevent central venous line-associated bloodstream infections were published in 2011.<sup>27</sup> The use of a greater than 0.5 percent chlorhexidine gluconate with alcohol is recommended as a skin preparation with the use of either 10 percent povidone iodine or 70 percent alcohol as alternatives if chlorhexidine gluconate is contraindicated. A chlorhexidine impregnated sponge dressing may be utilized if central line bloodstream infections (CLBSIs) are not decreasing in the institution. The use of antiseptic- or antimicrobial-impregnated central venous catheters and antimicrobial locks are options to be considered if a comprehensive CLABSI reduction plan has not reduced the rate of infection.

Any needed dental work should be completed before therapy is administered. Patients who smoke should be strongly encouraged to quit or at least reduce their consumption because smoking can increase the severity of a variety of respiratory viral illnesses and can exacerbate mucositis induced by chemotherapy or radiation. Any chronic skin, scalp, or nail bed condition should be addressed and brought under control as much as possible before rendering the immune system more compromised.

Potential recipients of solid organ transplant should be screened in advance of the transplant for latent infection. The aims of such screening are fourfold:<sup>28</sup> (1) to determine the immune status of the recipient against common pathogens that can be transmitted by transplants (this is because established immunity against pathogens, such as cytomegalovirus, *Toxoplasma gondii*, and possibly HBV, protects the recipient from severe sequelae of infection with these agents); (2) to permit the allocation of organs from donors infected with a certain pathogen to recipients who are already carriers of this agent, such as HCV infection; (3) to recognize and possibly treat infections that can be expected to exacerbate or reactivate after immunosuppression, such as tuberculosis, the endemic mycoses histoplasmosis and coccidioidomycosis, or parasites, such as *Strongyloides stercoralis*; and (4) to avoid transplantation in patients with a poor prognosis after transplantation, such as advanced HIV infection or colonization with a multidrug-resistant organism.



## AUGMENTATION OF HOST RESISTANCE

### Gastric Acidity

Gastric acid is an important defense mechanism against bacterial pathogens and, in general, should not be neutralized in an immunocompromised patient. With a normal gastric acid barrier, the majority of ingested pathogens never reach the intestinal tract to cause disease. Neutralization of this barrier may increase the susceptibility to and severity of a variety of bacterial and parasitic diseases,<sup>29,30,31,32,33,34,35</sup> including *Clostridium difficile*.<sup>37</sup> In the hospitalized patient, the stomach can serve as a reservoir for overgrowth of healthcare-associated Gram-negative bacteria when acidity is neutralized.<sup>23,38</sup> These bacteria may serve as a reservoir for aspiration after regurgitation.<sup>23</sup>

### Immunizations

Patients should be up to date on all routine immunizations.<sup>39,40</sup> The Advisory Committee on Immunization Practices (ACIP) divides patients with immunocompromising disorders into three practical categories: group 1, patients with HIV infection; group 2, patients with severe immunosuppression not caused by HIV; and group 3, patients with other conditions that cause limited immune deficits, such as asplenia, renal failure, diabetes, and alcoholism. In general, inactivated vaccines can be administered to patients in all three categories. Live virus vaccines are generally contraindicated in all patients in group 2, in some patients in group 1, and in no patients in group 3. The ACIP has recently published a recommended immunization schedule by age group and medical condition.<sup>41</sup>

Herd immunity against *Streptococcus pneumoniae* has developed in regions of the United States since introduction of the protein conjugate vaccine for children. This has resulted in marked decreases in the rate of invasive pneumococcal disease among adults, including those who are immunocompromised.<sup>42,43</sup>

The logical extension of these regional observations is to improve the use of protein conjugate pneumococcal vaccines in children in other communities. In addition, it is recommended that all persons with conditions associated with decreased immunologic function and increased risk for severe pneumococcal disease or its complications should be vaccinated.<sup>44,45,46,47,48,49,50,51,52,53,54,55,56,57</sup>

Although the vaccine is not as effective for immunocompromised patients as it is for immunocompetent persons, the potential benefits and safety of the vaccine justify its use.<sup>165</sup>

### Immunization in Recipients of Transplanted Organs (Autologous or Allogeneic Bone Marrow Transplants, Solid Organ Transplants)

Despite the burden of illness due to vaccine-preventable diseases in transplant recipients, licensed vaccines remain underutilized. One reason for this may be concern that immunization might trigger allograft rejection. Several recent studies have shown the lack of excess incidence of rejection and the general safety of vaccinations in organ transplant recipients.<sup>59</sup>

In general, vaccines are more likely to be effective in persons whose immune system is functioning normally than in a compromised host. The more compromised the host, the less effective the vaccine is likely to be. For transplant patients of all types, therefore, it is desirable to update all immunizations in advance of a transplant.<sup>60,61</sup>

Recipients of transplanted marrow or stem cells experience severe immunosuppression for several months after transplantation. This immunosuppression occurs regardless of the type of graft (autologous, syngeneic, or allogeneic), the underlying disease, the conditioning and preparative regimens, and whether graft-versus-host disease (GVHD) develops. Even in the absence of GVHD, reconstitution of a fully functioning immune system occurs slowly during the course of several months to years. Thus, interest is considerable in modalities to prevent infection during the period after transplantation. The literature supports the use of vaccinations, and standard preparations can be used effectively. Poor responses to vaccination can be expected for at least the first 6 months after transplantation. Detailed recommendations have recently been published for immunization of hematopoietic stem cell transplant recipients.<sup>62</sup> Recommendations include the use of tetanus/diphtheria; *Haemophilus influenzae* type B; Hepatitis B; 23 valent *Streptococcus pneumoniae* vaccine; inactivated polio vaccine; annual influenza (beginning  $\geq 6$  months after transplantation); and at 24 months after transplant, use of varicella vaccine, as well as measles, mumps, and rubella (MMR) vaccine (assuming no active GVHD or immunosuppressive therapy).

Because of the ongoing use of immunosuppressive medications, solid organ transplant recipients are at risk of life-threatening infections indefinitely. Specific vaccinations have been recommended for these patients, to include pneumococcal, influenza, *Neisseria meningitidis*, and Hepatitis A and B. Also indicated are tetanus, diphtheria, and *H. influenzae* type B. The safety of live attenuated vaccines is unknown. Some of them are absolutely contraindicated, including oral polio, vaccinia, bacillus Calmette-Guérin, and live oral typhoid. Yellow fever vaccine is not recommended.<sup>63</sup> Varicella vaccine is not recommended. Specific vaccination recommendations for solid organ transplant recipients have recently been published.<sup>61</sup>

### **Passive Immunization With Either Intramuscular or Intravenous Immunoglobulin**

The administration of preformed donor antibody by either the intramuscular or intravenous route has a long-established role in the prevention of infection. It is indicated as postexposure prophylaxis in susceptible patients exposed to such diseases as Hepatitis A, Hepatitis B, tetanus, rabies, and varicella. Intravenous immunoglobulin (IVIG) has been used for the treatment of primary and secondary antibody deficiencies for decades.<sup>63,64,65</sup> Many other potential uses have been investigated or are currently under investigation. Human trials of IVIG to prevent infections in high-risk postoperative, trauma, and burn patients have been inconclusive.<sup>66,67</sup> Similarly, IVIG-based treatment and prophylactic strategies for bacterial sepsis have yielded inconsistent results. A systematic review in 2002 concluded that current evidence is inconclusive regarding the clinical benefit of adjunctive IVIG therapy for the treatment of sepsis and septic shock,<sup>68</sup> and the most recent recommendations for the treatment of sepsis do not recommend their use.<sup>69</sup> IVIG is not generally recommended for routine oncology patients but may be indicated in selected patients with chronic lymphocytic leukemia and hematopoietic stem cell transplant recipients. The studies performed in patients with chronic leukemia showed a reduction in infectious episodes occurring in patients with less than 600 mg/dL of immunoglobulin G with monthly IVIG administration, provided it was performed for a minimum of 6 months.<sup>70,71,72,73,74</sup> Trials performed in hematopoietic stem cell transplant recipients demonstrated that, in the absence of hypogammaglobulinemia, monthly administration of IVIG did not reduce late complications and might impair long-term humoral recovery after transplantation.<sup>75</sup> Because of the several controversies that still exist regarding the use of IVIG in these populations, such as cost, availability of the product, and appropriate doses, the suggestions of Egerer et al.<sup>76</sup> are reasonable: use of 250 to 400 mg/kg every 4

weeks in patients with marked hypogammaglobulinemia and with more than two recent severe infections.

IVIg is being used increasingly for a variety of infectious and noninfectious disorders, including acute inflammatory disorders, hematologic disorders, autoimmune diseases, and neuroimmunologic disorders.<sup>63</sup> An expert panel has published consensus guidelines for the use of therapeutic IVIg.<sup>77</sup> The U.S. Food and Drug Administration (FDA) has approved the use of virus-specific monoclonal antibodies against respiratory syncytial virus and cytomegalovirus.<sup>63</sup>

### ***Granulocyte Transfusions***

The transfusion of donor leukocytes to augment resistance in chemotherapy-induced neutropenia was once commonly used. However, minimal benefit was gained, primarily because of the small numbers of granulocytes that could be harvested from donors. In addition, adverse reactions were common, including fever, alloimmunization, and transmission of CMV.<sup>78</sup> For these reasons, granulocyte transfusion became relatively uncommon.

Recent developments, including improved donor screening and use of colony-stimulating factors to improve the harvest from donors, could lead to increased use of granulocyte transfusion in a subset of the neutropenic population. The patients most likely to benefit from this would be those with profound and sustained neutropenia or neutropenic patients with infection not responding to antimicrobial therapy.<sup>79</sup> However, a review of 66 observational studies of granulocyte transfusions in neutropenic children (age, 1–18 years) performed over 30 years showed no evidence of a positive benefit risk ratio.<sup>80</sup> And a Cochrane review performed in 2003 found inconclusive evidence from randomized controlled trials to either support or refute the use of this modality. Heterogeneity between studies and methodological deficiencies presented significant obstacles to their review. The authors concluded, "contemporary well designed prospective trials are required to evaluate the efficacy of this intervention in these patient populations and to establish definitively whether it has clinical benefit. In such studies, average numbers of collected granulocytes for adults should be at least greater than  $1 \times 10^{10}$ ."<sup>81</sup> Because of the short half-life of granulocytes, which necessitates daily transfusion; the technical difficulties; and the discomfort to the donor of harvesting techniques, as well as improved chemotherapeutic regimens and availability of colony-stimulating factors, it is unlikely this modality will become commonly utilized, but it may be useful in selected patients.

### ***Colony-stimulating Factors***

The colony-stimulating factors (CSFs)—granulocyte colony-stimulating factor (G-CSF, filgrastim), pegylated G-CSF (pegfilgrastim), and granulocyte/macrophage colony-stimulating factor (GM-CSF, sargamostim)—have been evaluated for prophylactic use following the administration of chemotherapy when neutropenia is anticipated. The limited data available do not demonstrate a difference between the use of filgrastim and that of sargamostin.<sup>82</sup> Pegfilgrastim has a prolonged half-life, permitting either a single dose or once weekly dosing versus daily dosing. The agent is considered equivalent in efficacy to filgrastim.<sup>82</sup> The American Society of Clinical Oncology (ASCO) updated its guidelines for the use of these agents in 2006.<sup>83</sup> The committee unanimously agreed that reduction in febrile neutropenia is an important clinical outcome that justifies the use of CSFs, regardless of the impact on other factors, when the risk of febrile neutropenia is approximately 20 percent or higher (unlikely with most commonly used regimens). Use of CSFs as primary prophylaxis is recommended for patients who are at high risk for

febrile neutropenia based on age, medical history, disease characteristics, and myelotoxicity of the chemotherapeutic regimen. In addition, the use of CSFs allows a modest to moderate increase in the dose density or dose intensity of chemotherapeutic regimens.<sup>83</sup>

There is now a widespread consensus that prolonged filgrastim therapy represents the standard of care for relatively rare primary neutropenic disorders, such as severe congenital neutropenia, cyclic neutropenia, and symptomatic idiopathic neutropenia.<sup>63</sup> The use of CSFs in the nonneutropenic host to augment neutrophil function in established infection is a topic of great interest; however, the results in clinical trials in humans have been modest or discouraging. In community-associated pneumonia, a double-blind trial of filgrastim versus placebo in 756 patients showed no overall difference in mortality or length of hospitalization.<sup>84</sup> However, the incidence of adult respiratory distress syndrome was lower in the treatment group. In addition, in the subgroup with multilobar disease, the incidence of empyema or organ failure was 5.8 percent in the treatment group versus 17.1 percent in the placebo arm. Unfortunately, two subsequent trials of septic patients with pneumonia failed to demonstrate reductions in either mortality or complications.<sup>85</sup><sup>86</sup> In a small study of severe foot infections in diabetics, more rapid healing was reported in the group receiving filgrastim for 7 days than that receiving placebo.<sup>87</sup> The use of immunomodulatory agents is an area of active research, with several agents currently undergoing trials to include macrophage CSF, type I interferon, gamma interferon, and interleukins 1, 2, 10, and 12.

63

## REDUCTION OF EXPOSURE TO PATHOGENS

### *Isolation and Hand Hygiene*

In the majority of circumstances, standard isolation guidelines<sup>88</sup> are sufficient for protection of most immunocompromised hosts, if they are followed strictly and are accompanied by good hand hygiene. Hand hygiene has been the focus of extensive research recently, summarized in the Centers for Disease Control and Prevention's (CDC) *Guideline for Hand Hygiene in Health-Care Settings*.<sup>89</sup><sup>90</sup>

Compliance among healthcare personnel with guidelines for isolation and hand hygiene continues to pose a challenge.<sup>89,90,91,92</sup> Adherence to published guidelines is especially important when dealing with the immunocompromised host.

Reverse isolation has been extensively studied in the granulocytopenic patient. Most studies that showed improved outcomes for patients in reverse isolation did not adequately control for other variables. When careful hand hygiene is utilized and food and supplies are handled appropriately, reverse isolation offers no additional benefit in reducing infection in the typical granulocytopenic patient,<sup>93</sup><sup>94</sup> so for the typical neutropenic patient, there no longer appears to be a role for this modality.

Recent CDC Isolation Guidelines<sup>88</sup> recommend the use of a protective environment for allogeneic hematopoietic stem cell transplant patients. The need for such controls has been demonstrated in studies of *Aspergillus* outbreaks associated with construction. Components of the protective environment include such engineering designs as high-efficiency particulate air (HEPA) filtration of incoming air, directional air flow with positive room air relative to the corridor, well-sealed rooms to prevent flow of air from the outside, ventilation to provide more than 12 air changes per hour, scrubbable surfaces rather than upholstery and carpet, and routinely cleaning crevices and sprinkler heads.<sup>95</sup>



## Prophylactic Antimicrobials

Patients at risk for development of pneumonia caused by *Pneumocystis jiroveci* should receive prophylaxis with trimethoprim-sulfamethoxazole (TMP/SMX) for the duration of that risk. Alternatives for allergic patients include dapsone or atovaquone by mouth and pentamidine given by inhalation.

Multiple studies have demonstrated the efficacy of prophylactic antibiotic administration to patients with neutropenia.<sup>96</sup> However, the appropriateness of regular use of this modality has been called into question for three reasons. First, antibiotic prophylaxis has not been shown to consistently reduce mortality rates. Second, the potential exists for deleterious effects from toxicity and fungal overgrowth. Third, use of antimicrobials has been shown to cause the emergence of antibiotic-resistant bacteria.<sup>96,97,98</sup> Thus, whereas the evidence for use of prophylaxis would be enough to warrant an A-I recommendation (good evidence to support a recommendation for use based on evidence from one or more properly randomized, controlled trials), the guidelines for the past several years<sup>96-99</sup> as well as recent textbooks<sup>100-101</sup> have not recommended the routine use of antimicrobials for prophylaxis against bacterial infection.

Still, the issue remains unsettled. Subsequent to publication of the 2002 IDSA guidelines<sup>96</sup> a meta-analysis of 95 randomized trials in afebrile neutropenic cancer patients of antibiotics versus placebo found a decreased risk for death with only a nonsignificant increased risk for colonization with resistant bacteria.<sup>102</sup> On the other hand, a large, randomized, double-blind, placebo-controlled comparison of levofloxacin from the time of initiation of chemotherapy until neutrophil recovery failed to document a survival benefit.<sup>103</sup> Not addressed in these trials is the clear association with escalation in the rates of use of extended spectrum fluoroquinolones and development of diarrhea caused by *C. difficile*, particularly the new and more virulent NAP1 strain.<sup>104</sup> Thus, at this time, it appears prudent to utilize antibiotic prophylaxis in a selected and judicious fashion, rather than for all patients rendered neutropenic by chemotherapy.

Among those who might be more reasonable candidates for antibiotics include those whose underlying disease or the nature or intensity of the chemotherapy place them at much higher risk for infection. This includes patients whose chemotherapy will result in severe mucositis and prolonged or profound neutropenia ( $<100$  neutrophils/mm<sup>3</sup>). The use of certain drugs, such as alemtuzumab and pentostatin; multiple myeloma treated with myelosuppressive chemotherapy; and hematopoietic cell transplantation are also in this category.<sup>82</sup> Finally, personal factors, such as willingness to comply with prescribed prophylaxis, personal hygiene habits, and environmental (hospital or home) circumstances, should be considered.<sup>96</sup> If prophylaxis is considered, TMP/SMX and fluoroquinolones have been studied the most extensively. Antibiotics, if given, should be given for as short a period as possible.<sup>96</sup>

Antifungal drugs have similarly been employed as prophylaxis in neutropenic patients. In a meta-analysis of 64 randomized trials, systemic antifungal prophylaxis was associated with a decrease in all-cause mortality and invasive fungal infection mortality. However, for acute leukemia patients the reduction in all-cause mortality was only borderline significant.<sup>105</sup> Regarding which antifungal agent to employ, Cornely et al.<sup>106</sup> compared fluconazole, itraconazole, and posaconazole in a randomized multicenter trial of 602 patients with leukemia or myelodysplastic syndrome who had prolonged neutropenia due to chemotherapy. Posaconazole was associated with significantly fewer cases of invasive aspergillosis, and survival was significantly greater in the group receiving this drug. However, serious adverse events,

primarily gastrointestinal, were significantly higher in the posaconazole group.<sup>106</sup> Although these data suggest benefit, concerns similar to those with antimicrobials of the development of drug resistance need to be taken into consideration. In addition, the risk of invasive fungal infections is relatively low compared with that of bacterial infections. For these reasons, antifungal prophylaxis should be considered on a case-by-case basis with individual patients, taking into consideration the specific type of malignancy, the intensity of chemotherapy, and patient comorbidities, such as age, mucositis, diabetes, and smoking.<sup>82</sup>

### ***Prevention of Healthcare-associated Pneumonia***

Recognition in advance of the patients who are at greatest risk for development of pneumonia is critical to prevention. Intubation and mechanical ventilation alter first-line defenses. Therefore, such patients are at the highest risk of development of healthcare-associated pneumonia. Other risk factors are age older than 70 years; chronic lung disease; depressed consciousness; aspiration; chest surgery; the presence of an intracranial pressure monitor or nasogastric tube; H<sub>2</sub> blocker or antacid therapy; transport from the intensive care unit (ICU) for diagnostic or therapeutic procedures; previous antibiotic exposure, particularly to the third-generation cephalosporins; reintubation; hospitalization during the fall or winter; mechanical ventilation for acute respiratory distress syndrome; and frequent ventilator circuit changes.<sup>107</sup>

Most cases of healthcare-associated pneumonia occur by aspiration of bacteria colonizing the patient's oropharynx or upper gastrointestinal tract. Factors that tend to increase the colonization of the oropharynx include coma, hypotension, acidosis, azotemia, alcoholism, diabetes mellitus, leukocytosis, leukopenia, pulmonary disease, nasogastric or endotracheal tubes, and receipt of antimicrobials.<sup>19</sup> The use of chlorhexidine, but not oral application of antibiotics for topical antisepsis of the oropharynx, reduces the incidence of ventilator-associated pneumonia.<sup>108,109</sup> However, mortality was not improved.

Selective decontamination of the digestive tract has been studied extensively. This strategy aims to decrease the incidence of pneumonia by preventing gastric colonization with healthcare-associated bacteria and *Candida* spp. A variety of regimens have been utilized, including application of antibiotics topically to the oropharynx, administration through a nasogastric tube, or systemic administration. Whereas randomized trials and two meta-analyses suggest that this modality has benefit in reducing healthcare-associated pneumonia,<sup>107</sup> concerns about the emergence of resistant bacteria has limited the popularity of selective digestive tract decontamination.<sup>110</sup>

Patients who are placed in a semirecumbent position have a lower incidence of hospital-associated pneumonia than do patients who are supine.<sup>111</sup> For intubated patients, drainage of subglottic secretions limits the incidence of ventilator-associated pneumonia, particularly among patients expected to require more than 72 hours of mechanical ventilation.<sup>112</sup> Silver-coated endotracheal tubes have been demonstrated to reduce the incidence of ventilator-associated pneumonia in patients intubated for more than 24 hours. However, no differences were found in the duration of intubation, duration of stay in the ICU, duration of hospitalization, or overall mortality.<sup>107,113</sup> The robustness of the findings was modest, and the trial was not blinded. In the editorial review of this trial, it was suggested that the subset of intubated patients who are at very high risk of developing early-onset ventilator-associated pneumonia may be the group to benefit from this modality.<sup>114</sup>

The American Thoracic Society and the Infectious Disease Society of America, in their most recent guidelines, emphasize the following modalities for prevention of healthcare-associated pneumonia: effective infection prevention measures, including staff education, compliance with hand hygiene, and isolation to reduce cross-contamination with multidrug-resistant organisms; surveillance of ICU infections; avoidance of intubation and reintubation; body positioning in the semirecumbent position; use of enteral rather than parenteral nutrition; daily lightening of sedation; use of either sucralfate or H<sub>2</sub>blockers if needed for stress ulcer prophylaxis; limitation of red blood cell transfusion; and intensive insulin therapy to maintain serum glucose levels between 80 and 110 mg/dL in ICU patients.<sup>110</sup>

## Water

Water is a reservoir and a source for healthcare-associated infections.<sup>115</sup> Several commonly encountered pathogens are able to replicate in tap water, including include aerobic Gram-negative bacteria, such as *Pseudomonas* spp., *Legionella* spp., and nontuberculous mycobacteria. The reservoirs of concern include drinking water, sinks, faucet aerators, showers, tubs, toilets, dialysis water, ice and ice machines, flower vases (see following discussion), eyewash stations, and dental unit water stations. Several examples are found in the literature of environmental water reservoirs being associated with infection involving aerosolization from those sources, including faucet aerators associated with *Pseudomonas* infections and showerheads associated with legionellosis.<sup>116</sup> Those of theoretical concern for infection in the immunocompromised host include potable water, ice and ice machines, tubs for immersion, and, in hospitals with high rates of healthcare-associated *Pseudomonas* and *Legionella* spp. infections, faucet and shower aerators.<sup>115</sup> Highly immunocompromised patients (i.e., those who are utilizing some version of a neutropenic diet; see following discussion) should consider ingesting filtered or sterile water, use ice made from the same source, and avoid immersion in tubs.

## Food

Fresh fruits and vegetables carry several species of Gram-negative rods as part of their natural flora.<sup>117</sup> Shooter et al.<sup>117</sup> performed cultures on a variety of foods from eight hospitals in the London area. Foods sampled included salads, cold meat, cold sweets, other cold foods, hot food, and pureed food. A significant proportion of salads were found to carry *P. aeruginosa*, *Escherichia coli*, and *Klebsiella* spp. Furthermore, the majority of positive cultures yielded more than 1,000 colonies per gram of food.<sup>117</sup>

Organisms colonizing fruits and vegetables have been shown to colonize the gastrointestinal tract of neutropenic patients after ingestion<sup>119</sup> and food has been implicated in both colonization and invasion in immunocompromised patients.<sup>120</sup> The neutropenic diet, also called the cooked food diet or the low-bacterial diet, was devised to reduce the introduction of potentially pathogenic bacteria into the gut by the restriction of certain foods, particularly uncooked fruits and vegetables.<sup>121,122,123</sup> This modality continues to be widely employed. Smith and Besser<sup>124</sup> surveyed 400 hospitals associated with the Association of Community Cancer Centers regarding use of the neutropenic diet. Among the 156 hospitals responding to the survey, 78 percent used some version of the neutropenic diet. Most of these diets restrict fresh vegetables, fruits, and juices.<sup>124</sup> Despite the popularity of this diet, its effectiveness has not been rigorously evaluated, and many have begun to question whether the existing evidence supports continued use of this intervention.<sup>125</sup> This becomes important because many components of the neutropenic diet would be appealing choices for patients undergoing chemotherapy who may be



experiencing nausea, altered taste sensation, and mouth sores.<sup>125</sup> Thus, the concern is that use of a neutropenic diet may contribute to poor nutrition without providing any benefit to the patient. Historically, when a neutropenic diet was combined with skin cleansing, topical and oral nonabsorbable antibiotics, and a laminar airflow room, serious bacterial infections have been avoided.<sup>126</sup> When the diet is studied alone, there is mounting evidence of its lack of effectiveness. Moody et al.<sup>127</sup> performed a pilot study in children comparing the neutropenic diet to safety guidelines approved by the FDA, which emphasizes common sense and good hygiene advice. Among the 19 patients, the infection rates were similar.<sup>127</sup> A larger study performed in adults randomly assigned 153 patients to a diet containing no raw fruits or vegetables to a diet containing these items. Twenty-nine percent of patients in the cooked food group and 35 percent of patients in the raw food group developed a major infection ( $p = .60$ ); the time to major infection and survival time were similar in the two groups. Fever of unknown origin occurred in 51 percent of the cooked food group and 35 percent of the raw food group.<sup>128</sup>

The CDC, the Department of Health and Human Services (HHS), and the U.S. Department of Agriculture (USDA) do not endorse the neutropenic diet in cancer patients with neutropenia.<sup>127</sup> Instead, they offer food safety guidelines that emphasize common sense, good hygiene, and clean water. The recommendations include hand hygiene; washing fruits and vegetables; cooking meat, fish, and poultry to well done; reheating deli meats and hot dogs to steaming hot; and avoidance of vegetable sprouts and rough skinned fruits, such as raspberries and strawberries and unpasteurized juice and dairy products. However, broad elimination of raw, washed fresh fruits and vegetables is not a standard part of federal guidelines.<sup>129-130</sup>

Although a hospital kitchen occasionally may be the source of food contamination,<sup>120</sup> agents of gastroenteritis and Hepatitis A are much more likely to be encountered in food purchased in a restaurant.<sup>131</sup> For hospitalized immunocompromised patients, restriction of food to controllable sources where adherence to USDA guidelines is assured is advised. Bringing in food prepared in the home should be done only with approval of the attending physician.

### ***Plants and Fresh Flowers***

It is well established that both potted plants<sup>132</sup> and fresh flowers<sup>133-134</sup> carry microbial flora that are pathogenic for the immunocompromised host. Taplin and Mertz<sup>133</sup> detected gentamicin-resistant Gram-negative rods in 23 of 75 vases tested in a burn unit and associated the removal of these flowers with a decrease in wound colonization. Kates et al.<sup>134</sup> examined the microbial flora of vase water from cut flowers obtained from hospital environments, restaurants, and flowers grown in private gardens. A total of 41 different bacterial species were identified, including many common healthcare-associated bacterial species. Overall, 90 percent of the isolated organisms were known as causative agents of infection. High levels of resistance to multiple antimicrobials were found in the organisms irrespective of their source, indicating that multiple-resistant microbial flora found in vase water is indigenous to flowers, rather than originating from the healthcare environment. The colony count of water from vases rose steadily over time. The authors postulated that the hands of healthcare personnel becoming transiently colonized while changing vase water could serve as a potential source for infection.<sup>134</sup>

Because of data such as these, most bone marrow transplant units do not allow flowers or live plants to be brought into patients' rooms.<sup>135</sup> A recent study found that introducing fresh flowers into the rooms of

nonneutropenic, non-bone marrow transplant patients did not increase the number of fungi isolated.<sup>136</sup>

The recommendations made by Kates are reasonable: Ban flowers from high-risk areas, such as cancer wards and burn units; designate the handling of flowers to support staff with no patient contact or, when this is not feasible, wear gloves when handling flowers; wash hands after contact with plant material; change the vase water at least every 48 hours; dispose of vase water into designated sinks that are not in the immediate environment of the patient; and thoroughly disinfect vases after use.<sup>134</sup>The

immunocompromised patient should strive to avoid direct contact with cut flowers or living potted plants of any type and should perform hand hygiene with an alcohol-based gel if such contact occurs.

## Visitors

The healthcare team should ensure that visitors are properly screened for infections and instructed about the importance of proper infection prevention precautions, especially proper hand washing in advance of interacting with the patient. All visitors should be instructed to follow the same standard precautions as healthcare personnel.<sup>88</sup>Visitors who currently have a diagnosed illness that is

communicable by airborne, droplet nuclei, or contact routes or who have symptoms of upper respiratory infection or diarrhea should be discouraged from visiting the patient. If visitation does take place, appropriate precautions should be employed.<sup>88</sup>

Pediatric visitors may carry and transmit disease unknowingly,<sup>137</sup>and thus it is advisable that visitors younger than 12 years be permitted only with physician approval, even if they appear healthy. Children should be screened for known illness or exposure in the previous 4 weeks to varicella, rubella, rubeola, mumps, Hepatitis A, group A streptococcal pharyngitis, pertussis, viral respiratory infection, undifferentiated diarrhea, vomiting, fever, rash, or live virus immunization (MMR, varicella, or polio).<sup>138</sup> Patients should perform hand hygiene with an alcohol-based hand gel after interaction with any pediatric visitors.

## Pets

The American Pet Product Manufacturer's Association estimates that nearly 63 percent of American households have at least one companion animal and that the total number of pets in the United States is approximately 360 million. The majority of these continue to be dogs and cats, but rabbits, birds, and reptiles make up an increasing number of pets in the home.<sup>139</sup>Forty-one percent of dogs share their owners' beds.<sup>140</sup>The list of potential diseases transmitted to owners from such traditional pets has included such agents as *Campylobacter*, *Bartonella*, *Cryptosporidium*, *Giardia*, *Salmonella*, and *Toxoplasma* spp.<sup>141</sup>In addition, there are nearly 40 bacteria that have been isolated from dog and cat bite wounds.<sup>142</sup>An increasing number of persons are obtaining nontraditional or exotic pets, including rodents, reptiles, prairie dogs, nonhuman primates, ferrets, animals caught in the wild (raccoons, pigeons), and animals imported, both legally and illegally, from foreign countries (i.e., Gambian pouch rats [*Cricetomys gambianus*], African hedgehogs [*Atelerix albiventris*], sugar gliders [*Petaurus breviceps*], axolotls [*Ambystoma mexicanum*], and others).<sup>139,141</sup>Thus, more agents must be added to the list of potential infectious diseases transmissible from pets to people such as, for instance, *Escherichia coli* O157:H7,<sup>143</sup>monkeypox,<sup>144</sup>Cercopithecine herpes virus,<sup>145</sup>*Francisella tularensis*, *Leptospira* spp. rabies, and *Yersinia pestis*,<sup>139</sup>as well as diseases transmitted by the mites, fleas, and ticks associated with some of these animals. Pet therapy has been advocated as psychologically beneficial to

hospitalized patients<sup>146,147</sup> and to nursing home residents.<sup>148</sup> There is a paucity of literature on the true risk to immunocompromised patients of exposure to pets, and a survey of 20 pediatric oncology centers in the United Kingdom revealed that only 4 used either published or locally developed guidelines regarding pet ownership.<sup>141</sup> Potential transmission routes to immunocompromised hosts include inhalation of infectious aerosols; contact with urine, saliva, or feces; and bites or scratches. Common sense dictates the following: Exotic pets or pets without a known pedigree (i.e., may have been illegally imported) should not be allowed. Pets that are allowed to visit a patient should be housebroken (i.e., no puppies or kittens), tame, docile, up to date on all vaccinations, and pronounced disease free by a veterinarian. Pets should be kept cleaned and brushed, and nails clipped short to minimize the risk of scratches. Patients should perform hand hygiene after contact with pets of any kind (hand washing with antiseptic soap if exposure has occurred to organic material, otherwise alcohol-based hand gels are acceptable). Hand hygiene performance in children should be supervised. In addition, scratches and bites should receive immediate attention, including disinfection, regardless of how trivial the injury appears.

**Table 23-2** Latent Organisms and Their Geographic Distribution

Organism	Geographic Distribution
Mycobacterial <i>M. tuberculosis</i> <i>M. avium complex</i>	Worldwide, especially in urban centers and developing countries Ubiquitous in the environment
Fungal <i>Histoplasma capsulatum</i> <i>Coccidioides immitis</i> <i>Blastomyces dermatitidis</i> <i>Pneumocystis jiroveci</i> <i>Penicillium marneffei</i>	Central river valleys of the United States Desert Southwest Mississippi and Ohio River basins Worldwide Southeast Asia
Bacterial <i>Pseudomonas pseudomallei</i>	Southeast Asia, South Pacific
Protozoal <i>Strongyloides stercoralis</i> <i>Toxoplasma gondii</i>	Tropics and the Southern United States Worldwide
Viral <i>Herpes group viruses</i> <i>JC papovavirus</i>	Worldwide Worldwide

Certain circumstances raise particular concern regarding pet visitation. Patients who have had a splenectomy are at high risk for invasive infection by *Capnocytophaga canimorsus*, a Gram-negative bacterium that is part of the normal oral flora of dogs. Because pets can act as fomites for the transmission of bacteria between patients, patients who are placed in contact isolation should not be allowed to interact with animals. Some animals pose an unacceptable risk of diseases, such as rabies in skunks, raccoons, and bats; *Cercopithecine herpesvirus* (B virus) in Asian macaques; and *Salmonella* carriage in turtles, lizards, and snakes. These animals should be excluded from the hospital and not be part of any pet therapy program. As a result of asymptomatic urinary excretion of *Leptospira* spp. (dogs and others) and lymphocytic choriomeningitis virus (LCM) (mice and hamsters), careful hand hygiene is necessary after exposure to the urine of these animals. A recent series of organ transplant recipients contracted LCM either from the organ donor or the environment of the organ donor. Seven of the eight recipients died of the disease.<sup>149</sup>

## Prophylaxis Against the Emergence of Endogenous Infections

A variety of organisms have the capacity to establish latency within the body once an infection has been established. This establishment may occur with symptomatic clinical illness (i.e., primary varicella, herpes simplex, others) or without clinical illness (i.e., *M. tuberculosis*, *P. jiroveci*). These latent infections may reactivate during immune compromise. Table 23-5 lists the most important microorganisms that establish latency, as well as their geographic distribution. Some agents can be detected serologically (*C. immitis*, *T. gondii*) or by skin testing (*M. tuberculosis*). Under certain circumstances, it is appropriate to offer prophylaxis against these infections to reduce the incidence of their reactivation to cause clinical disease. For instance, HIV-infected individuals with CD4 cell counts of less than 200/mL are recommended to receive prophylaxis against *P. jiroveci*. Individuals with previous exposure to *M. tuberculosis* undergoing treatment with tumor necrosis factor inhibitors should receive prophylaxis with isoniazid.<sup>150</sup>

## Conclusions

Care of the immunocompromised host poses tremendous challenges. Those challenges include identification of compromised patients and determining their net state of immunosuppression, anticipating the microbial pathogens of unique concern for their type of immune deficit, augmenting their innate resistance to opportunistic infection, and early identification of infection such that appropriate therapy can be instituted. The infection prevention issues include prevention of acquisition of potential pathogens as well as prevention of reactivated infection from affecting other individuals. New therapies continue to evolve, and novel pathogens continue to be discovered.<sup>10,151,152</sup> Well-supported guidelines now exist for care of patients in a variety of circumstances. Optimal approaches to other circumstances are yet to be defined completely, leading to the need for extrapolation and the use of clinical experience. Effective methods for overcoming such obstacles as emerging drug resistance and failure of healthcare personnel to adhere to basic hygiene techniques also are lacking. Cost-effectiveness and appropriate outpatient locations for healthcare delivery are additional areas of study.

Treatment decisions often need to be made in situations where no formal guidelines exist. In such situations, the recommendations discussed here are reasonable based on the literature that exists. In the individual patient, these guidelines should be applied carefully, taking into consideration the specific situation and the net state of immunosuppression of the patient. Careful follow-up of the immunocompromised patient is important because infection can rapidly become fulminant.

## Future Trends

### PROBIOTICS

The term *probiotics* refers to the medicinal use of viable organisms to cause beneficial effects on a host. The Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) have stated that there is adequate scientific evidence to indicate that there is potential for probiotics to provide health benefits and that specific strains are safe for human use.<sup>153</sup>

Whereas the comprehensive review of the literature by the FAO and WHO demonstrated a relatively small number of areas in which probiotics have proven antidisease effects, preliminary investigations have been promising for their use in enhancing mucosal immunity, treating surgical wound infection, reducing the incidence of certain malignancies, and reducing the duration of diarrhea. Most studies have



been small, and many have important methodological limitations. In addition, considerable differences exist in composition, dose, and biologic activity among various commercial preparations, so comparison of results between studies is often difficult or impossible. The FDA approves no probiotic. These may not always be benign agents. A critically ill patient with diarrhea was given *Saccharomyces boulardii* as a probiotic and developed invasive disease.<sup>154</sup> Large, well-designed, multicenter controlled trials are needed to clarify the role of different probiotics in different patient populations. The interested reader is referred to the review by Reid et al.,<sup>155</sup> the online posting of the Working Group report of the FAO and WHO,<sup>153</sup> and a recent *Clinical Infectious Diseases* supplement<sup>156</sup> for a discussion of the potentials of this modality.

## VACCINATIONS

Tremendous advances in vaccine technology have been made in the past decade, and although many of these advances have been directed toward the traditional definition of a vaccine, namely the prevention of an infectious disease, new technologies have extended the scope of vaccinations to include treatment of established disease as well. Targets for vaccines outside the field of infectious diseases continue to expand and now include cancer, addiction, cardiovascular disease, gastrointestinal disease, autoimmune disease, prevention of drug toxicity, and fertility. The implications of this line of research for the many kinds of immunocompromised patient are significant. A detailed discussion of these issues provides fascinating reading.<sup>157</sup>

## IRRADIATION OF FOOD PRODUCTS

Despite ongoing efforts of public health agencies and food growers, processors, and manufacturers to reduce the risk of foodborne diseases, every year in the United States foodborne diseases cause approximately 76 million illnesses, 225,000 hospitalizations, and 5,000 deaths.<sup>158</sup> A substantial portion of those illnesses are borne by immunocompromised patients. Food irradiation or "cold pasteurization" of solid foods with low doses of rays, x-rays, and electrons can effectively control bacterial and parasitic pathogens, even at extremely low levels of contamination.<sup>158</sup><sup>159</sup> Consumption of foods prepared in these ways has been shown to be safe.<sup>159</sup> The WHO has endorsed food irradiation, as have the CDC, the USDA, and the FDA. An increasing list of foods has been approved by the FDA to undergo irradiation, including recently spinach and lettuce, and there are approximately 60 commercial irradiation facilities available in the United States.<sup>160</sup> Food irradiation for the general public or for the immunocompromised host has yet to be embraced fully. With efforts to educate the public about irradiation of food, consumer acceptability may improve.<sup>161</sup>

## STATINS

Inhibitors of the enzyme HMG CoA reductase, commonly referred to as statins, have been utilized for years to reduce cholesterol and lipid levels. Independent of their lipid-lowering abilities, statins have been demonstrated to modulate the inflammatory response associated with infection.<sup>162</sup> Animal models demonstrated that the administration of a statin before a sepsis-inducing insult reduces morbidity and improves survival.<sup>163</sup> An observational cohort study of 361 consecutive patients admitted to an ICU with presumed or documented acute bacterial infection demonstrated that severe sepsis developed in 19 percent of the group not taking statins and only 2.4 percent of those who were receiving one.<sup>164</sup> In the

near future, randomized, controlled clinical trials will define if statins have a role in preventing or reducing complications of infection.

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## Microbiology Basics

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### Abstract

*Microbiology is the study of organisms too small to be seen by the naked eye. Clinical microbiology encompasses the study of pathogens such as bacteria, viruses, fungi, and parasites that cause disease or infection in humans. Issues of concern in clinical microbiology include the nature and epidemiology of etiological agents, how they interact with the immune system, rapid diagnosis, and providing information on treatment, such as antimicrobial susceptibility.*

*Fundamental knowledge of microorganisms, their identification, significance, and basic laboratory techniques provide the infection preventionist with an understanding of pathogenic organisms. This chapter includes an overview of microorganisms, clinical laboratory methods that are used to evaluate the presence and/or significance of microorganisms, and methods to analyze the relatedness of microorganisms for epidemiological purposes.*

### Key Concepts

- Certain qualities of microbes lie at the root of many infection prevention issues, including their extremely small size, rapid reproductive rates, and resistance to harsh environmental conditions.
- The clinical microbiology laboratory is an important partner in the practice of infection prevention.
- The clinical microbiology laboratory can provide information on microbes determined to be of clinical significance.
- Proper specimen collection and transport are integral to the recovery of valid microbiological information.
- The presence of microbes in a clinical specimen does not always indicate the presence of infection.
- A variety of methods can be used to identify bacteria, fungi, and viruses.

- Antimicrobial susceptibility testing is commonly used to assist in the selection of appropriate antimicrobial therapy. Monitoring resistance patterns is an important function of the clinical microbiology laboratory.
- The clinical microbiology laboratory is an important collaborative partner during outbreak investigations and situations requiring environmental sampling.

## Essential Knowledge for the Prevention of Infections

Infection prevention procedures can be understood if the IP knows and imparts the following to others:

1. Bacteria are astoundingly small; it is difficult to imagine that something can be so small yet be alive. Contemplate that if a typical size bacterium was placed every second into a 1-mL container then it would take over 30,000 years to fill the container. The implications of this calculation are suffering and even death; consider that an almost invisible crack in equipment such as an endoscope could contain numerous bacteria, such as *Clostridium difficile*, that could enter a patient. The infection preventionists who understand this about bacteria will be able to more effectively convince hospital staff of the need for elaborate cleaning and sterility procedures.
2. The reproduction rate of many species of bacteria is as astounding as their small size. About 30 minutes are required for a bacterium of some species to divide into two bacteria and another 30 minutes for the two to divide into four, etc. If sufficient nutrients were available to the growing population then it could produce a trillion bacteria within 20 hours and soon after that, calculations show, a mass of bacteria equal to the mass of the earth could be produced; of course nutrients are not available for such growth. The implications to the infection preventionist are again suffering and death; if even a very few of the unimaginably small living bacteria enter a vulnerable patient then, within a short time, the bacteria have the potential to grow into a dangerous population.
3. Some bacteria, for example, those of the genus *Clostridium*, can transform into endospores that can survive in water heated to well above boiling temperature, are resistant to drying, are resistant to harsh chemicals, and can be dispersed in dust. These characteristics make cleaning medical equipment and facilities difficult tasks that must be done thoroughly.

## Scope of Microbiology

The field of microbiology includes the study of bacteria, fungi (molds and yeasts), protozoa, viruses, and algae. Infection preventionists are likely to encounter most of these microbe types in the course of their practice with the exception of algae. Structure and identification of bacterial species is described first, followed by fungi and viruses.

### BACTERIA

#### CLASSIFICATION

There are at least 17 groups of bacteria according to one classification scheme that is based in large part on nucleotide sequences of RNA. All of these groups have a similar cell structure that is known as "prokaryotic." Prokaryotic cell structure is microscopically characterized by lack of a visible nucleus, by the lack of a membranous nuclear envelope, and by lack of membrane-bound internal structures such as mitochondria.<sup>1</sup>

## IDENTIFICATION

There is no agreed-upon definition of species in bacteriology.<sup>2</sup> Nevertheless, bacteria have binomial names that are generally referred to as species names that are essential to the work of the infection preventionist. Using *Staphylococcus aureus* as an example, notice that it is written in italic letters (or underlined to indicate italic letters). The first term of the name is known as the genus name and the second term is the specific epithet; both names are essential to name a species. The genus name can be used alone but the specific epithet cannot be used alone. Techniques and characteristics used to identify species and subspecies are discussed in the Clinical Microbiology subsection of this chapter.

## CELL STRUCTURE AND ARRANGEMENT

Bacteria are very small, single-celled organisms. They contain a single long circular molecule of double-stranded DNA. This "bacterial chromosome" is not surrounded by a nuclear envelope and is attached to the plasma membrane. In addition to the bacterial chromosome, bacteria often contain small circular, double-stranded DNA molecules called plasmids. Although plasmids are not necessary for cell survival in a normal environment, they may carry genes for activities such as antibiotic resistance, production of toxins, and synthesis of enzymes. Plasmids can be transferred from one bacterium to another and genes may move from plasmid to chromosome. These genes are called transposable genetic elements or transposons. Bacteria also contain ribosomes that function as the site of protein synthesis. The plasma membrane encloses the cytoplasm of the cell and provides selective permeability for nutrients to enter.<sup>3</sup>

The cell wall of bacteria is a complex, semirigid structure responsible for the shape of the cell. It surrounds the underlying, fragile plasma membrane and protects it and the interior of the cell from the environment. The cell wall is made of a macromolecular network called peptidoglycan. In most Gram-positive bacteria, the cell wall consists of many layers of peptidoglycan, forming a thick rigid structure. By contrast, Gram-negative cell walls contain only one (or very few) layers of peptidoglycan. Gram-negative cells possess an outer membrane that is composed of lipoproteins, lipopolysaccharides, and phospholipids. This outer membrane helps some organisms evade phagocytosis, provides a barrier to certain antibiotics, and confers properties of virulence (endotoxins). Glycocalyx is a general term used for widely varying chemical substances that surround cells. If the glycocalyx is organized and firmly attached to the cell wall, it is referred to as a capsule. Capsules may contribute to bacterial virulence and may offer protection from phagocytosis. If the glycocalyx is unorganized and only loosely attached to the cell wall, it is called a slime layer.<sup>1</sup>

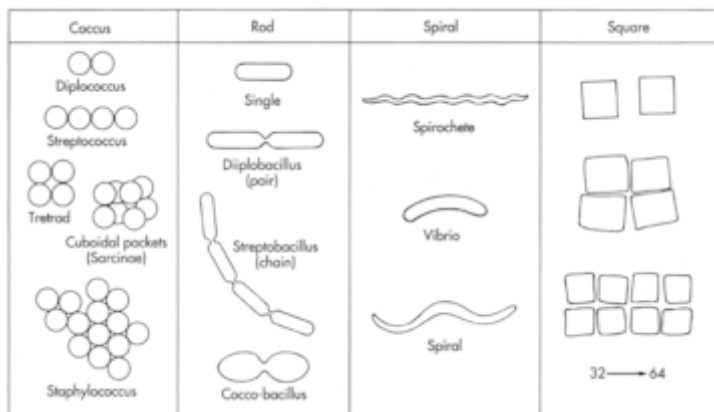
Some bacteria have flagella that are long filamentous appendages that propel the cell. Many Gram-negative bacteria possess hairlike appendages that are used for attachment rather than for motility. These are divided into two types, fimbriae (singular, fimbria) and pili (singular, pilus). Fimbriae enable a bacterial cell to adhere to surfaces (including other cells), whereas pili join bacterial cells in preparation for the transfer of DNA from one cell to another.<sup>1</sup>

Cell shape and arrangement are easily microscopically observed for many species (Figure 24-1). For example, *Streptococcus* and *Staphylococcus* are more or less spherical cells; *Staphylococcus* can be differentiated from *Streptococcus* by cell size and arrangement. *Streptococcus* spheres tend to form chains, whereas *Staphylococcus* spheres tend to form clumps. *Escherichia coli* cells on the other hand are rod-shaped.

When essential nutrients are depleted, certain Gram-positive bacteria (e.g., *Clostridium* and *Bacillus*) form structures known as endospores. Endospores are composed of nuclear material and protein. Endospores are remarkable for their ability to survive in water heated to above boiling temperature, for their ability to survive extreme drying, and their ability to survive exposure to some toxic chemicals. When growth conditions permit, the endospores transform into more typical bacteria known as the vegetative form. An example of this is seen with *Clostridium difficile*-associated diarrhea. When the patient has active diarrhea, the feces contains both the vegetative and endospore forms of the bacteria. Once shed from the body, vegetative bacteria form endospores that are not easily killed by high temperatures, detergents, or disinfectants that are used to clean equipment and facilities. When endospores encounter a favorable environment, such as the interior of a human intestine, they can transform into vegetative cells that are capable of reproduction.<sup>1</sup>

## BACTERIAL REPRODUCTION

Bacteria normally reproduce by binary fission, with one cell dividing into two cells. The rate of division can vary from slow (*Mycobacterium tuberculosis* may replicate every 12 to 24 hours) to rapid (*E. coli* cells, for example, may divide every 20 minutes under ideal environmental conditions). The first step in division is cell elongation and replication of chromosomal DNA. The cell wall and cell membrane begin to grow inward near the middle of the cell eventually meeting to form a cross-wall; thus, two individual cells are formed. These "daughter cells" are essentially identical to the parent cell.<sup>1</sup>



**Figure 24-1.**

Characteristic bacterial cell shapes and arrangements. There are many sizes and shapes among bacteria. Most range from 0.2 to 2.0  $\mu\text{m}$  in diameter and 2 to 8  $\mu\text{m}$  in length. They have a few basic shapes: spherical coccus (plural, cocci), rod-shaped bacillus (plural, bacilli), and spiral. Cocci are usually round but can sometimes be irregularly shaped. Cocci that remain in pairs after dividing are called diplococci; those that remain attached in a chain are called streptococci; and those that remain

attached in clusters or broad sheets are called staphylococci. Most bacilli appear as single rods and are fairly uniform in shape. However, some bacilli are oval and look so much like cocci they are called coccobacilli. Spiral bacteria have one or more twists. Bacteria that look like curved rods are called vibrios; others that look like corkscrews and have fairly rigid structures are called spirilla; and those that are helical and flexible are called spirochetes.

[View Image](#)



## BACTERIA GENETIC DIVERSITY

Daughter cells produced by binary fission are thought to be genetically identical, except for mutants that result from random mistakes during DNA replication. Genome change can occur not only by mutation but also by transfer of genes from other bacteria. For example, acquisition of an R plasmid can render a bacterium and its descendants immediately resistant to antibiotics if resistance genes are encoded on the plasmid; plasmids can also encode toxins that may render the microbe pathogenic. Plasmids are DNA molecules that are generally circular and not essential to the microbe under some environmental conditions.<sup>1</sup>

Bacteria are known to obtain new combinations of genes in several ways.<sup>1</sup>

1. Transformation occurs when naked DNA in the environment, possibly from dead bacteria, enters another bacterium. The transferring DNA either may be incorporated into existing chromosomal DNA or, if the transferred DNA is a plasmid, become part of the plasmid DNA pool.
2. Conjugation occurs when all or part of a plasmid is transferred from a donor to a recipient cell. The cells must be in direct contact and transfer occurs via the sex pilus. Conjugation can occur between widely separated species, leading to the rapid dissemination of genetic information (e.g., antibiotic resistance genes).
3. Transduction occurs when bacterial DNA is transferred from a donor cell to a recipient cell via a virus capable of infecting bacteria.

## Mycoplasma

*Mycoplasma* is a genus-containing species that are extremely small pleomorphic bacteria (0.2 to 0.8 µm). They lack cell walls and are surrounded only by an outer plasma membrane. Because they lack a rigid cell wall, they are resistant to cell wall-active antibiotics (e.g., penicillins and cephalosporins). Mycoplasmas can be grown on artificial media that provide them with sterols (exogenous cholesterol) and other special nutritional or physical requirements. Because colonies are extremely small, cell culture methods are often used. Although there are approximately 70 species of mycoplasmas, not all are associated with human disease. Organisms associated with human infection include *Mycoplasma pneumoniae* (atypical pneumonia or walking pneumonia), *Ureaplasma urealyticum* (urogenital tract infections), and *Mycoplasma hominis* (urogenital infections)<sup>4,5</sup> (also see **36. Pneumonia**, and 91 Sexually Transmitted Diseases).

## Chlamydiae

Chlamydiae are a group of bacteria that are obligate intracellular parasites. They are Gram-negative coccoid, ranging in size from 0.2 to 1.5 µm. Chlamydiae display a growth cycle that takes place in host cells. The bacteria invade the cells and differentiate into dense bodies called reticulated bodies. The reticulated bodies reproduce and eventually form new chlamydiae in the host cell called elementary bodies. These elementary bodies lyse the host cell and begin a new infection cycle. Organisms associated with human infection include *Chlamydia trachomatis* (male and female genital tract infection, causes lymphogranuloma venereum), *Chlamydia pneumoniae* (pneumonia, pharyngitis, risk factor for Guillain-Barré syndrome), and *Chlamydia psittaci* (causes psittacosis or parrot fever)<sup>1,4,5</sup> (also see **36. Pneumonia**, and 91 Sexually Transmitted Diseases).

## Rickettsiae

Rickettsiae are a group of bacteria that are obligate intracellular parasitic bacteria. They are Gram-negative rod-shaped bacteria or coccobacilli (0.8 to 2.0 µm long) that divide by binary fission. Rickettsiae infect humans as well as arthropods, such as ticks, mites, and lice. Infection is transmitted to humans through the bite of an infected arthropod. Rickettsiae have not been grown in cell-free media; however, molecular diagnostics can detect rickettsiae in tissues. Diagnosis is usually achieved using antibody testing (Weil-Felix agglutination test, latex agglutination test), microimmunofluorescence test on



serum, or immunofluorescent staining of tissue biopsy specimens. Organisms causing human infection include *Rickettsia rickettsii* (Rocky Mountain spotted fever), *Rickettsia prowazekii* (epidemic typhus), *Rickettsia typhi* (endemic [murine] typhus), *Ehrlichia canis* (Ehrlichiosis), and *Coxiella burnetii* (Q fever).<sup>1,4,5</sup>

## FUNGI

Fungi are eukaryotic organisms. The term eukaryotic indicates that they have a nucleus that is distinctly visible with a light microscope and that is surrounded by a nuclear envelope. The nucleus is typically spherical or ovoid, about 6 µm in diameter. Relative size of fungi compared to bacteria can be appreciated by calculating that about 200 spheres the size of a *Streptococcus* bacterial cell could be fit into the nucleus of a typical fungus cell.

Fungi derive nutrients from organic materials. Fungal cell walls contain a chemical substance known as chitin. Some fungi are well-adapted human pathogens (e.g., *Candida albicans*). Most, however, are accidental pathogens that humans acquire through contact with decaying organic matter or airborne spores in the environment. Typically, fungi may be divided based on the appearance of the organism into two separate groups: yeasts and molds (see also **78. Fungi**).

### YEASTS

Yeasts are single-celled microscopic organisms. In culture, yeasts usually form a smooth, creamy colony. They have a single nucleus with a nuclear membrane and contain organelles. They typically reproduce by a process of budding. In this process, a parent cell forms a "bud" on its outer surface. As the bud elongates, the parent cell's nucleus divides and one nucleus migrates into the bud. Eventually, the cell wall closes between the parent cell and the bud, and the bud breaks free. Some yeasts reproduce through the process of fission, similar to bacterial reproduction.<sup>7</sup> Common pathogenic yeasts include *Candida* spp. (mucositis, vaginitis, dermatitis, systemic dissemination) and *Cryptococcus neoformans* (meningitis, pneumonia in compromised hosts).

### MOLDS

Molds consist of long, branching filaments of cells called hyphae. A tangled mass of hyphae visible to the naked eye is a mycelium. Aerial mycelium gives mold a fuzzy or woolly appearance in culture. The hyphae's physical characteristics, such as shape (e.g., antler, racquet, or spiral), pigmentation, and the presence of rootlike structures called rhizoids are used to differentiate and identify molds. Some molds reproduce asexually by fragmentation of their hyphae. Additionally, molds may reproduce sexually and asexually by the formation of spores. Asexual spores are formed by the hyphae of one organism. When these spores germinate they become organisms identical to their parent cell. Sexual spores result from fusion of nuclei from two opposite mating strains of the same species of fungus. Organisms that grow from sexual spores have characteristics of both parental strains. Common opportunistic pathogenic molds include *Aspergillus* spp. (invasive pulmonary aspergillosis) and agents of mucormycosis (e.g., *Rhizopus* and *Mucor*).<sup>4</sup>

### DIMORPHIC FUNGI

Some fungi exhibit dimorphism and can grow as either a mold or yeast form. The moldlike forms produce vegetative and aerial hyphae; the yeastlike forms reproduce by budding. Typically, dimorphism in fungi is temperature dependent: At 37°C the fungus is yeastlike, and at 25°C it is moldlike. Common pathogenic dimorphic fungi include *Histoplasma capsulatum* (acute pulmonary histoplasmosis, disseminated infection), *Blastomyces dermatitidis* (chronic skin infections, pulmonary lesions), and

*Coccidioides immitis* (respiratory tract, meningeal infection). *Pneumocystis carinii*, previously classified as a parasite, was recently reclassified as a fungus based on DNA characteristics. *P. carinii* (now named *Pneumocystis jirovecii*) is a major cause of pneumonia in acquired immunodeficiency syndrome (AIDS) and other immunosuppressive conditions.<sup>6</sup>

### IDENTIFICATION OF FUNGI

Depending on the type of organism, some fungi can be identified directly from a clinical specimen. For example, a skin scraping may be directly examined for the presence of fungal hyphae (may require special staining techniques). Additionally, some yeasts, especially *Candida* spp., grow on routine blood agar and require no special culture techniques. Yeasts such as *Candida* can be identified to the species level through a series of tests, including germ-tube tests (positive, *C. albicans*) and sugar assimilation (done manually or in an automated instrument).

In some cases, cultures need to be done to identify and classify potential fungal pathogens. A selective media such as Sabouraud (suppresses the growth of bacteria) is generally used for culturing fungus. The specimens are usually incubated at room temperature (25°C to 30°C) for several weeks. Identification of fungal isolates is based on the appearance of the colony and on microscopic examination.

In addition to culture, other methods exist to identify the presence of certain fungi. Direct antigen detection methods (e.g., latex agglutination) may be used to identify *C. neoformans*. Serologic test methods can be used to identify coccidiomycosis microbes, histoplasmosis microbes, and *Aspergillus* spp.

## EUKARYOTIC PARASITES

Human parasites vary greatly in size and complexity. They may be single-celled microscopic protozoa or multicellular worms over 10 feet in length. Protozoa are unicellular, free-living eukaryotic organisms. Most protozoan parasites exist in two different forms: the pleomorphic trophozoite stage (feeds, and produces effects in the host) and the cyst stage (most responsible for transmission). Other types of parasites include flukes, tapeworms, roundworms, and ectoparasites such as lice and scabies (see also **99. Parasites**).

Microscopy is the cornerstone of most parasite diagnosis. Direct or concentrated examination of stool, urine, vaginal secretions, or duodenal aspirates may yield protozoans or eggs of helminths. Specific identification is based on characteristic morphological appearance. Direct antigen detection methods have been developed for giardiasis and are widely used. Serological test methods may be performed when direct examination of tissue is difficult or unrevealing. These tests are usually conducted by reference laboratories and may be useful in diagnosing parasitic infections such as amebiasis, schistosomiasis, cysticercosis, echinococcosis, and malaria (also see **99. Parasites**).

## VIRUSES<sup>8</sup>

Viruses are not considered to be cells; therefore, they are not classified as either eukaryotes or prokaryotes. They are obligate intracellular parasites, which means that they grow and reproduce within living cells and are dependent on the cells' synthetic and metabolic machinery. Viruses are too small to be seen with a light microscope (therefore they are sometimes said to be ultramicroscopic), although they may be visualized with an electron microscope. Virus particles contain nucleic acid (either RNA or DNA) surrounded by protein and, in some cases, other components such as a membrane-like envelope. Originally, viruses were classified by their type of host and the type of diseases caused (e.g., human poliovirus). With the advent of genetic testing, viruses are now classified in families and genera based

on genome type (RNA or DNA), the number of strands in the genome (double-stranded [ds] or single-stranded [ss]), morphology, and the presence or absence of an envelope.

### *VIRUS REPRODUCTION*

Outside the host cell, the virus particle is known as a virion; it is metabolically inert and does not grow or multiply until it enters a living cell. Viruses in general replicate in a similar fashion, which occurs in five steps:

1. *Attachment.* The virion attaches to a complementary receptor site on the host cell. Virus attachment is specific; for example, Epstein-Barr virus attaches to receptors on B lymphocytes.
2. *Penetration.* The virion enters the host cell through a process called endocytosis, which means that the host cell engulfs the virus rather like it brings food molecules into a cell.
3. *Replication.* Viral DNA or RNA directs the host cell to begin synthesis of viral components. Viral replication uses host cell ribosomes, energy sources, and amino acids to produce these components.
4. *Maturation.* The viral components essentially assemble into viral particles spontaneously forming daughter virions.
5. *Release.* The host cell lyses or the virus buds through the cell wall and the daughter virions are released. Some viruses lie dormant in the host cell for months or years; after this latent period, new virions form and cause damage to host cells.

### *VIRUS IDENTIFICATION*

There are three major methods to diagnose viral infections: direct detection in the clinical specimen, specific antibody assay to detect viral antibodies in the serum, and viral culture. Direct detection methods include: (1) electron microscopy, which is used primarily by reference laboratories; (2) enzyme-linked immunosorbent assay (ELISA) for viruses such as respiratory syncytial virus (RSV), Hepatitis B surface antibody, and rotavirus; (3) latex agglutination for viruses such as rotavirus and RSV; (4) DNA probes for viruses such as cytomegalovirus (CMV); (5) polymerase chain reaction (PCR) for DNA detection for viruses such as HIV types 1 and 2; (6) optical immunoassay (OIA), an antibody antigen-based test that produces a reflection change for detection of influenza viruses A and B from respiratory specimens; (7) light microscopy of cell scrapings from infected sites can detect Cowdry type A inclusion bodies from herpes simplex virus and varicella zoster virus; (8) Papanicolaou (Pap) smears for the effect of human papillomavirus on squamous cells; and (9) Negri bodies for the diagnosis of rabies.

Viral infections cause an immunogenic response; therefore, antibody detection methods can be useful in the diagnosis of infection. Simple antibody tests can determine the presence or absence of immunoglobulin (Ig). This can be used to determine if a patient has ever been infected with a specific virus (e.g., varicella, adenovirus). Complex antibody detection systems use a battery of viral antigens and often distinguish IgM (early) from IgG (late) antibodies.

Specific antibody detection has some inherent issues that can limit effective use of this methodology, including:

- Measurement of the patient's response to the virus and not actual detection of the virus
- Antibody production varies based on the patient's immune system
- Antibody level does not necessarily correlate with acuteness or activity level of the disease state
- Testing is most often retrospective as diagnosis by paired sera requires both acute and convalescent samples

- There is the possibility of cross-reaction with nonspecific antibodies
- There is the possibility of passive transfer of antibodies transplacentally or after transfusion

Advantages of serological testing methodology include diagnosis of viral infection from nonculturable organisms (e.g., hepatitis viruses); confirmation of immune status for diseases such as rubella, measles, varicella, and Hepatitis B; and usefulness in epidemiological or prevalence studies.

### *VIRUS CULTURE*

Virus culture traditionally requires specialized media containing antibacterial and antifungal agents prepared in plastic or glass tubes and flasks. Clinical specimens are cultured on an array of different mammalian cell culture lines, depending on the agent suspected clinically. Growth is viewed microscopically and is identified through changes in the host cells rather than as discrete viral "colonies." Although tissue cultures are still considered to be the gold standard, many viral infections are diagnosed through other rapid methods. Advantages of viral culture include sensitivity, detection of many types of viruses, adaptability to viral variation, and options for susceptibility testing.<sup>9</sup>

## Clinical Microbiology

The presence and identification of organisms in a clinical specimen may be indicative of infection. The primary goals of clinical microbiology are to identify the presence of pathogenic organisms in tissues, body fluids, excretions, or secretions and to identify those pathogens to species level based on morphological and biochemical properties. Additional goals are to predict response to antimicrobial therapy and assist in epidemiological investigations. Often, the first step to identify microbes is preparation of a slide to examine the clinical sample microscopically. Another necessary procedure in bacteria identification is preparation of pure cultures. (Note that not all microbes can be visualized with a microscope nor can all be cultured in the hospital laboratory.)

### MICROSCOPE SLIDE PREPARATION

In order to observe clinical or culture materials through a microscope, the specimen must be prepared for observation. In some cases, the specimen may be placed onto a slide for direct observation. Some fungi and parasites are large and distinct enough to be examined directly (e.g., protozoa, *Cryptococcus* India ink). However, most observations are made with stained preparations.

Direct examination or direct wet mount of clinical specimens should be performed as soon as possible after collection; consequently, it is often performed in the clinic or ambulatory care setting. Because some materials are very thick, they require dilution with sterile saline; however, this practice increases the risk of aerosolization and should be performed in a biosafety cabinet. Types of specimens examined by direct wet mount include sputum, drainage from lesions, body fluid aspirates, stool, vaginal discharge, and urine sediment. Examples of pathogens identified by direct wet mount include the motile trophozoites of *Giardia lamblia* in stool, *Trichomonas vaginalis* in vaginal discharge or urine sediment, or *Entamoeba histolytica* from a liver abscess aspirate.

Before microorganisms can be stained they must be fixed (attached) to a microscope slide. A thin film of material is spread over the surface of a slide. This "smear" is then fixed with either heat or chemicals. Fixing the smear not only ensures that the organisms are attached to the slide, but also kills the organisms, making the slide safe to handle.

Once a specimen is received in the microbiology laboratory, it is assessed for potential microbial pathogens. In many cases, the specimen is placed into or onto special media to cultivate the growth of microbes. Once the microbe grows, further test methods are used to identify the microbe. Microbiologists can often make presumptive and very useful identifications just by examining a stained slide. However, reliable identification can be done only if pure cultures are prepared. There are usually a variety of microbes present in clinical specimens; this variety includes not only the suspected pathogen(s) but also commensal bacteria commonly found on and in the body.

## BACTERIA PURE CULTURES

A bacterial pure culture is a population of usually many millions that have reproduced from a single bacterium. To obtain a pure culture it is first necessary to isolate a single microbe from the clinical sample that has been sent to the microbiology laboratory for species identification. Isolation of a single bacterium could be a daunting task given that a clinical isolate might contain many bacteria. However, the streak plate technique makes the task easy.

### *STREAK PLATE*

To make a streak plate, the microbiologist must obtain a sterile solidified growth medium, containing appropriate nutrients, in a flat, shallow dish known as a Petri dish. Sterile implements are then used to spread the clinical sample over the surface of the plate in a way that ensures that individual bacteria in the sample are separated on the surface of the solid media. The streak plate is then incubated, usually overnight, until colonies have grown; each colony consists of millions of descendants of the original isolated bacterium.

The choice of the nutrients included in the Petri dish and the incubation conditions are critical to growth and identification of bacteria. The choice of media depends on the site being cultured (e.g., throat, blood, urine), the growth requirements of common or suspected pathogens, and the likelihood of normal flora (also known as commensal bacteria) being present. Commensal bacteria live in a relationship in which one organism derives food or other benefits from another organism without hurting or helping it (e.g., normal flora in the mouth). Most growth media are in agar form (a gelatin-like substance in a Petri dish). There are several categories of growth media including: (1) nutrient agar, a general purpose growth medium that supports the growth of a wide variety of bacteria (e.g., trypticase soy agar with 5 percent sheep blood); (2) enrichment medium, which contains special nutrients necessary for the growth of hard-to-grow (fastidious) bacteria (e.g., chocolate agar for the growth of *Neisseria meningitidis*); (3) selective media that contain chemicals or antibiotics designed to inhibit normal commensal bacteria, while allowing organisms of interest to grow (e.g., bismuth sulfate agar for the isolation of *Salmonella* spp.); and (4) differential media that stains colonies of specific organisms while growth inhibiting others (e.g., acetate agar to differentiate *E. coli* from *Shigella*). The atmospheric conditions chosen to incubate the streak plate are also crucial to the identification process. Bacteria that grow only in complete or nearly complete absence of ambient atmospheric oxygen and are inhibited or killed by oxygen are known as obligate anaerobes; these must be incubated in equipment that removes oxygen from the atmosphere. Organisms that have an absolute requirement for air (oxygen gas) and do not grow in the absence of oxygen are called aerobic organisms. Facultative anaerobes are organisms that can use oxygen if it is present but can grow without it. Aerobic and facultative organisms may be grown in normal atmospheric conditions. Microaerophilic organisms require oxygen in concentrations that are 2 to 10 percent of the normal atmospheric 21 percent oxygen; in addition, they may also require an increased carbon dioxide concentration.



Incubation temperature and time are also important. Most cultures are incubated at human body temperature (35°C). However, some are incubated at room temperature whereas others are incubated at 42°C. The streak plate is incubated, usually overnight, in a warm, moist environment although some bacteria may require a longer incubation.

## SOME OF THE CHARACTERISTICS USED TO IDENTIFY BACTERIAL SPECIES<sup>8</sup>

After bacterial colonies have grown on the streak plate, the identification process can begin. The atmosphere, the nutrients, and the temperature in which the colonies can grow are characteristics that can be used to identify the bacteria. Another set of characteristics includes the size of the colonies, the texture of the colonies (e.g., rough or smooth, etc.), the margin of the colonies (are the edges of the colony undulating, feathery, etc.), the color of the colonies (white, yellow, etc.), and the effect of differential media on the colonies (e.g., a medium may have been used that causes the colony of bacteria that can ferment the sugar named lactose to be a different color than the colonies of bacteria that cannot ferment lactose). Reaction of bacteria with stains such as the Gram stain, acid-fast stain, and others (see Staining Fundamentals below) also provide characteristics that can be used in species identification.

Other tests that may be used to rapidly identify species of bacteria include the catalase test used to differentiate streptococci (negative) from staphylococci (positive) and the coagulase test that is used to differentiate *S. aureus* (positive) from other staphylococci such as *S. epidermidis* (negative). For more precise identification of Gram-positive bacteria, a battery of biochemical tests may be performed. These tests may be conducted manually or commercially available kits and automated instruments may be used.

Gram-negative bacilli are generally tested for their ability to ferment the nutrient sugar named lactose. Lactose-fermenting Gram-negative bacilli are included in a biological group known as Enterobacteriaceae; non—lactose-fermenting Gram-negative bacilli include *Pseudomonas* spp. as well as *Proteus* spp. More precise identification of Gram-negative bacteria requires a battery of biochemical tests. These tests may be conducted as individual test tubes or be done by using commercially available kits and equipment.

## SOME ADDITIONAL TESTS USED TO CHARACTERIZE SPECIES AND SUBSPECIES

Species identification is insufficient when strains within the species may be isolated that have characteristics that affect treatment, such as antibiotic resistance. Furthermore, when tracing an outbreak, it is necessary to characterize below the species level to determine the source of an outbreak. For example, an outbreak of *Salmonella enterica* in a population may involve attempts to determine if *Salmonella enterica* in swine is related to the *Salmonella enterica* serovar 4[5],12:i:- that is isolated from patients.<sup>11</sup>

Historically, a variety of methods have been used to identify pathogenic microorganisms and evaluate their potential epidemiological interrelationships. In general, these methods have primarily relied on phenotypic (i.e., observable) characteristics. However, as test methods have advanced, more emphasis has been placed on genotypic methods (i.e., molecular or chromosomal) to determine if organisms isolated from different sources are related.

Biotyping characterizes microbes based on patterns of metabolic activities such as biochemical reactions, colony morphology, or nutritional and environmental requirements. Although biotyping can be used with any organism, it has limited ability to distinguish epidemiologically related organisms from unrelated organisms.<sup>8</sup>

Serotyping is based on the immunological (i.e., antisera) detection of specific antigenic determinants on the surface of bacterial cells. Serotyping is most commonly used with *Salmonella* spp., *Shigella* spp., and pneumococci. It is not as discriminating as genotypic analysis and requires maintenance of large stocks of typing antisera.<sup>1</sup>

Antimicrobial susceptibility testing may be used to determine if microbes are related. Although this type of testing is routinely performed in the clinical laboratory, it is relatively nonspecific and has limited usefulness in determining true relatedness.

Bacteriophage typing is useful only with bacterial species that are susceptible to infection and lysis by viruses (bacteriophages). The potential interrelationship between different bacterial isolates (i.e., the bacteriophage type) is assessed on the basis of bacteriophage lytic patterns.

Electrophoresis may be used to compare the rate of movement of metabolic enzymes or proteins from different isolates. This method assumes that minor differences in enzyme genes or proteins are reflected in their movement across the test gel. When the test gel is examined, related organisms have the same pattern of movement. Although this test method may be used with some bacterial pathogens, it is labor intensive and time consuming.<sup>8</sup>

Plasmid analysis compares bacterial isolates based on the presence of self-replicating extrachromosomal genetic elements (plasmids). Because plasmids often encode antibiotic resistance, clinical bacterial isolates frequently carry several different plasmid types. The bacterial cells are enzymatically lysed to release the plasmid DNA, which can then be analyzed by conventional agarose gel electrophoresis. This type of analysis may be used with common bacterial pathogens that frequently carry plasmids; however, many organisms are "nontypeable," as they do not carry plasmids.<sup>6</sup>

Restriction endonuclease enzymes can subdivide both plasmids and chromosomal DNA into smaller fragments. Using agarose gel electrophoresis, the smaller pieces of genetic material are separated into different-sized restriction fragments, which are compared to assess genetic relatedness. Unfortunately, because chromosomal patterns are composed of hundreds to thousands of restriction fragments, interpretation of results may be difficult.<sup>9</sup>

Southern blot analysis of restriction fragment length polymorphisms (RFLPs) is a method in which chromosomal DNA is extracted from clinical isolates and digested with restriction enzymes. Using gel electrophoresis, the restriction fragments are separated and transferred to a synthetic membrane. The fragments are then labeled with a homologous piece of DNA that acts as a probe to find complementary base pairs. Variations in the number and sizes of fragments detected are called RFLPs. This testing method may be used with any organism that has available defined probes, and the use of probes derived from genes for ribosomal RNA is termed *ribotyping*. One advantage of RFLP testing is that some probes may allow simultaneous assessment of epidemiological interrelationships and definition of other clinically relevant characteristics (e.g., mechanisms of antibiotic resistance or the presence of specific antibiotic resistance genes). Unfortunately, this method is time consuming, labor intensive, and technically difficult.<sup>12</sup>



Pulsed-field gel electrophoresis (PFGE) begins with the lysis of organisms and digestion of their chromosomal DNA with restriction enzymes. The fragments are separated into a pattern of discrete bands by switching the direction of the electrical current. This pattern serves as a "bar code" of the bacterial chromosome that can be used to assess the relatedness of different clinical isolates. This test method may be used with any organism from which chromosomal DNA can be properly isolated; it has been used with a wide variety of bacterial pathogens to assess epidemiological interrelationships. PFGE is probably the most widely used method for "molecular epidemiology" and is generally considered to be the gold standard for most clinically important organisms.<sup>13</sup>

Amplification techniques, such as PCR, are widely used in epidemiological investigation of healthcare-associated pathogens. In PCR, target DNA is extracted from the study organism. Short DNA molecules (primers), which specifically attach to each end of the target sequence, are added to the PCR reaction mixture along with a thermostable DNA polymerase and other reagents essential for DNA synthesis. In the PCR instrument (thermocycler), the target DNA is heated to denature it to single strands. After cooling, the primers attach to each end of the specific target sequence if it is present. DNA polymerase allows duplication (amplification) of the target DNA, resulting in two double-stranded molecules from each original sequence. After many cycles, millions of copies of the target sequence are produced that may be identified by a variety of means (e.g., electrophoresis, reaction with a specific probe, etc.). A number of other amplification methods that are variations of PCR procedures and testing methods are continually being developed. As new techniques are developed they must be assessed to determine their usefulness in epidemiological investigations.<sup>14</sup>

## MYCOBACTERIA IDENTIFICATION

Mycobacteria require special culture techniques to be isolated. In general, specimens undergo procedures to kill commensal bacteria that may be present. Once the specimen has been processed, it is planted on special media and incubated for 4 to 6 weeks.<sup>8</sup>After the organism grows, further testing must be conducted to identify the species (also see **95. Tuberculosis and Other Mycobacteria**).

Because conventional culture techniques may take weeks to recover mycobacteria, more rapid techniques have been developed. PCR methods have been developed. In this method, genetic chromosomal parts can be detected by DNA probes. DNA probes usually are used after the mycobacteria have been isolated from the culture.

### *MYCOPLASMA IDENTIFICATION*

Because of their fastidious growth requirements, *Mycoplasma* culture is a challenging process. In many species, growth is poor or absent even in complex media.<sup>1</sup>*M. hominis* may be grown from wounds using special media and from blood using radiometric techniques. In general, serological tests are used to diagnose *Mycoplasma* infection.

### *CHLAMYDIAE IDENTIFICATION*

Because of their parasitic nature, *Chlamydia* growth requires tissue culture and is not attempted in most laboratories. Direct-detection methods enjoy the greatest popularity for diagnosis. It is now possible to detect the antigen by direct fluorescent antibody slide staining and ELISA. Invasive infection does produce an immunogenic response. Therefore, *Chlamydia* antibodies can be measured using complement fixation, microimmunofluorescence, and ELISA techniques.

### *RICKETTSIAE AND OTHER TICKBORNE MICROBES IDENTIFICATION*

Because of their parasitic nature and host requirements, rickettsiae are rarely cultured. Early diagnosis is usually made on clinical grounds. Currently, serological studies are the most sensitive and specific tests for detection of specific infections (i.e., Lyme disease). ELISA is the best diagnostic test and determines specific levels of antibodies IgM and IgG.

## Microscopy

Because microorganisms are invisible to the naked eye, the essential tool in microbiology is the microscope. The microscope allows direct examination of clinical and culture materials. Also, it yields information on the presence, relative size and shape, and staining characteristics of microbes.

### LIGHT MICROSCOPE

The most commonly used microscope in the clinical laboratory is the light microscope. It is a compound microscope because it contains two types of lenses that function to magnify an object. The lens closest to the eye is called the ocular, whereas the lens closest to the object is called the objective. Most microscopes of this type have four objective lenses: the scanning lens (4 times magnification); the low-power lens (10X); the high-power lens (40X); and the oil immersion lens (100X). With the ocular lens that magnifies 10X, the total magnification will be 40X for the scanning lens and 1,000X for the oil immersion lens. (Be aware, however, that the quality of a microscope is not accurately described by its magnifying power; toy microscopes are often correctly advertised to magnify more highly than the best research microscopes!) Depending on the type of light source used to illuminate the slide (specimen), the compound microscope can be used in several ways.

Bright-field microscopy uses visible light sources and is the most common type of microscopy used in the clinical lab. This is the method regularly used to examine specimens that have been stained using the Gram stain method.

Dark-field microscopy is utilized to examine fresh material and permits observation of motile organisms that cannot be stained by common methods (e.g., treponemes, *Borrelia* spp.). This type of microscopy uses a special condenser and causes light to reflect off the specimen at an angle. Objects appear bright against a dark background and are better resolved than with a bright-field microscope.

Phase-contrast microscopy is helpful in direct observation of unstained material. It uses a special condenser that throws light "out of phase" and causes it to pass through objects at different speeds. This type of microscopy takes advantage of the different densities of cellular elements and makes them appear to stand out from their backgrounds. Phase-contrast microscopy is typically used for examination of living cells, particularly tissue cultures for viral isolation and identification.

The fluorescent microscope employs an ultraviolet (UV) light source. This type of microscopy depends on the ability of naturally fluorescent substances or dyes to absorb energy in nonvisible UV and short visible wavelengths, become excited, then emit energy in longer visible wavelengths. This method is very popular because of ease of interpretation of stained materials and the speed at which materials can be reviewed. Coupled with specific antibodies (e.g., direct or indirect fluorescent antibody [DFA or IFA] tests), rapid diagnoses of specific organisms can be made.

A fairly recent development in light microscopy is known as confocal microscopy. Specimens are stained with fluorochromes so they will emit or return light. A laser is used to illuminate the specimen. Most confocal microscopes are used in conjunction with a computer to construct three-dimensional images.

## ELECTRON MICROSCOPE

The energy source in the electron microscope is a beam of electrons produced by an electron-emitting tungsten filament. The extremely short wavelength of the electron beam, compared to visible light, increases the resolution of the microscope significantly. Viruses and some large molecules can be seen with this type of instrument. Special gold or palladium stains are used to prepare the specimens before viewing. Images are typically viewed on a computer monitor. Transmission electron microscopy (TEM) uses a finely focused beam, whereas scanning electron microscopy (SEM) sends the beam through an electromagnetic lens that allows for three-dimensional views. Because of the significant cost of electron microscopes and the specialized skills needed to operate them, they are rarely used in clinical laboratories but are useful as research tools.

## STAINING FUNDAMENTALS<sup>8</sup>

Staining specimens for microscope examination is one of the most useful techniques available in the microbiology laboratory. It rapidly provides the clinician with confirmation that the specimen is representative of the patient's condition (e.g., deep cough quality sputa vs. oral secretions or saliva), identifies the cellular elements within the specimen as well as inflammatory debris expected in the presence of an infection (e.g., white blood cells in cerebrospinal fluid), and can rapidly assist in presumptive identification of specific infectious agents (e.g., acid-fast stain for the detection of mycobacteria). Staining simply means coloring the microorganisms with a dye that emphasizes certain structures. Stains are usually acidic (negatively charged) or basic (positively charged) salts. Basic dyes react with nuclear cell components; acidic dyes react with cytoplasm and granules. Simple staining uses only one dye and may be used to demonstrate the shape, size, and arrangement of organisms or the presence of spores. Differential staining uses two or more dyes to demonstrate shape and biochemical color reaction. Differential stains react differently with various microorganisms and thus can be used to distinguish among them. They are used to divide nearly all bacteria into major groups. The most commonly used differential stains are the Gram stain and the acid-fast stain. Table 24-1 lists some stains commonly used in the clinical microbiology laboratory.

**Table 24-1.**Stains Commonly Used in the Clinical Microbiology Laboratory<sup>8</sup>

**Table 24-1** Stains Commonly Used in the Clinical Microbiology Laboratory

Stain	Application
Gram stain	Most bacterial species; bacteria can be grouped based on their Gram stain reactions; routinely used as the primary microscopic examination
Acid-fast stain Ziehl-Neelsen nonfluorescent	Direct smear for the detection of mycobacteria; identification of acid-fast organisms
Kinyoun nonfluorescent	Direct smear for the detection of mycobacteria, cryptosporidia, and <i>Cyclospora</i> parasites in stool
<b>Fluorochromes (fluorescent stains)</b>	Detection of cell wall-deficient bacteria such as mycoplasmas
Acridine orange	Detection of mycobacteria as well as some sporozoan parasites
Auramine-rhodamine	Direct smear for the differentiation of fungi from background materials; bronchoalveolar fungi and some parasitic cysts
Calcofluor white	Diagnostic antibody or DNA probe-mediated stains directed specifically at an organism
Immunofluorescent	

Modified toluidine blue O stain	Detect <i>Pneumocystis carinii</i> respiratory tract material as well as other parasites and fungi
Trichrome stain	Differentiates the internal structures of cysts, trophozoites, or other forms of parasites; useful for examination of stool specimens
Wright-Giemsa	Detect parasitic protozoan nuclei in blood (e.g., <i>Plasmodium</i> species, <i>Babesia</i> , <i>Trypanosoma cruzi</i> )

## Gram Stain

The Gram stain was developed in 1884 by the Danish bacteriologist Hans Christian Gram. The Gram stain is an important tool for the clinical microbiologist. Gram stain reaction, along with cell shape and cell arrangement, can be used to determine the type of media that should be used for culture, the appropriate identification procedures that should be done, and the types of antimicrobial testing that should be initiated. For these reasons, it is imperative that the microbiologist maintains a high degree of skill as well as a comprehensive quality assurance program. As stated earlier, Gram staining of a specimen with interpretation is important to clinicians. It may help to determine the quality of a specimen, initial direction for therapy (empiric), or the need for isolation precautions (e.g., Gram-negative diplococci in cerebrospinal fluid, suggesting meningococci).

Differences in cell wall structure influence the retention or loss of the combination of crystal violet/iodine complex. Gram-positive bacteria have a thick peptidoglycan cell wall (peptidoglycan is a name that indicates the chemical structure of the cell wall) that does not allow the crystal violet/iodine complex to be removed during the alcohol wash. Under the microscope, Gram-positive organisms appear dark violet, purple, or blue. Gram-negative bacteria contain a lipopolysaccharide layer as part of their cell wall. The alcohol wash disrupts this layer and the crystal violet/iodine complex is rinsed out of the cell wall. As a result, Gram-negative cells are colorless until counterstained with a red dye (safranin is usually used). Under the microscope, Gram-negative organisms appear pink or red. Some organisms absorb an increased amount of the stains and are said to have a strong avidity, whereas others are weakly stained and present a pale appearance (low avidity). Gram-negative enteric pathogens have a strong avidity to the safranin stain and are bright red. Pseudomonads are less avid and only uptake a moderate amount of safranin. Anaerobic bacilli and other thin-walled Gram-negative organisms (e.g., *Borrelia*, *Legionella*) stain weakly and appear pale red or pink. In addition to bacteria, many fungi and some protozoa and helminths stain with the Gram stain process. *Chlamydia*, *Rickettsia*, *Mycobacterium*, and *Nocardia* organisms stain poorly and may require special staining techniques for identification.

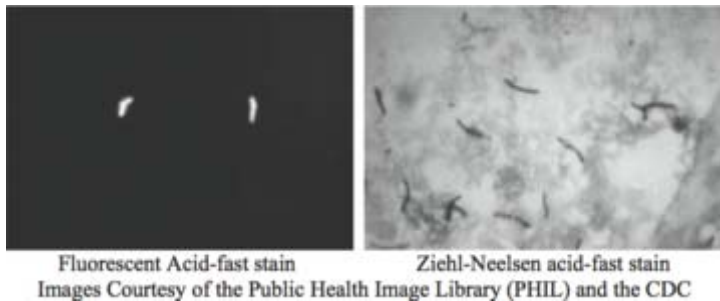
## Acid-fast Stain

Cells of certain bacteria and parasites contain long-chain fatty acids (mycolic acids) that make them impervious to crystal violet and other basic dyes. Heat or detergents can be used to force dye into this type of cell. Once this occurs, the cell cannot be decolorized by acid-alcohol, hence the term acid-fast. Acid-fast stains are very useful in identifying *Mycobacterium* spp., an acid-fast bacillus (AFB), as well as *Nocardia* and *Actinomyces* organisms.

Generally, one of two types of procedures is used for acid-fast stains: a fluorescent or a nonfluorescent stain. Both the Ziehl-Neelsen and Kinyoun nonfluorescent staining procedures use the red dye carbolfuchsin as the primary stain and methylene blue as the counterstain; however, the Ziehl-Neelsen process uses heat with the carbolfuchsin, whereas the Kinyoun process is a cold stain. Acid-fast organisms will retain the carbolfuchsin and will appear red under the microscope (where the AFB nickname "red-snapper" comes from) (see Table 24-1). The auramine-rhodamine method uses a fluorescent stain as the primary stain and acid-fast organisms exhibit bright yellow-orange fluorescence under UV light (see Figure 24-2). As the number of organisms shed by the infected patient can vary



greatly, the overall sensitivity of the acid-fast smear varies from 20 to 80 percent. In an effort to standardize reporting, the U.S. Department of Health and Human Services has published recommendations for the reporting and interpretation of acid-fast smears. It should be noted that the auramine-rhodamine fluorochrome stains are more sensitive than the carbolfuchsin stains.



**Figure 24-2.**

**A.**Fluorescent acid-fast stain. **B.**Ziehl-Neelsen acid-fast stain. (Images courtesy of the Public Health Image Library and the CDC)

[View Image](#)



#### *CALCOFLUOR WHITE STAIN*

Calcofluor white is used for rapid screening of specimens for fungal elements and pneumocystis cysts. This colorless dye binds to

the cellulose and chitin in the cell walls of fungi and fluoresces when exposed to UV light. Yeast cells, pseudohyphae, and hyphae display a bright apple green or blue-white fluorescence.

#### *MISCELLANEOUS STAINS*

Other staining procedures can be useful in identifying the presence of specific microorganisms. Immunofluorescent staining combines an antibody directed/probe which attaches to a specific organism with a dye that converts UV light into visible light. If the antibody binds with the organism, the organism fluoresces under the microscope. Immunofluorescent stains may be used to detect *Chlamydia*, *Legionella pneumophila*, *Bordetella pertussis*, herpes simplex virus, varicella-zoster virus, cytomegalovirus, adenovirus, and respiratory viruses from clinical specimens. The trichrome stain is useful in the identification of many fecal parasites. It is used to enhance the structures of protozoa, cysts, and some ova.

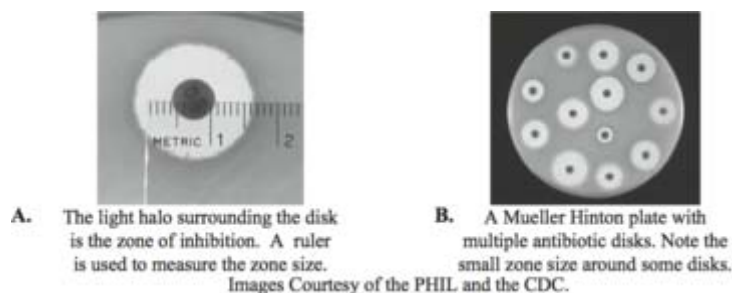
## Antimicrobial Susceptibility Testing

Antimicrobial therapy seeks to suppress (bacteriostatic) or kill (bactericidal) microorganisms by exploiting biochemical reactions unique to the pathogenic microbe. Ideally, this should be accomplished using the simplest agent with minimal toxicity to the patient. Originally, the purpose of susceptibility testing, sometimes referred to as sensitivity testing, was to determine whether the organism isolated was able to resist the effect of the therapeutic agent chosen for treatment. However, as processes have evolved, there are antimicrobial susceptibility testing (AST) methods available that directly measure the activity of one or more antimicrobial agents against a bacterial isolate, directly detect the presence of a specific resistance mechanism in a bacterial isolate, and measure complex antimicrobial-organism interactions. The type and extent of the AST conducted depends on the organism isolated, the source of the culture (body site), available antimicrobial agents, and typical susceptibility patterns. Several methods may be used for susceptibility testing.

### DISK DIFFUSION (KIRBY-BAUER METHOD)

Once a potential pathogen has been isolated by culture, a standardized suspension of bacteria is spread in a lawn fashion onto Mueller-Hinton agar. Paper disks impregnated with a standard amount of an antibiotic are placed onto the agar surface and the agar plate is incubated overnight. During incubation, the antibiotic diffuses out into the agar, resulting in decreasing concentrations of the agent

as it moves farther from the disk. Organism growth is either inhibited by the concentration of the antibiotic in the agar or not. That area in which the concentration of the antibiotic prohibits the growth of the organism is called the zone of inhibition (Figure 24-3).



**Figure 24-3.**

Disk diffusion antimicrobial susceptibility test.

**A.** The light halo surrounding the disk is the zone of inhibition. A ruler is used to measure the zone size. **B.** A Mueller-Hinton plate with multiple antibiotic disks. Note the small zone size around some disks. (Images courtesy of the Public Health Image Library

[View Image](#)



Measurements of the zone size have been standardized for each antibiotic/pathogen interaction and are used to interpret the effectiveness of that antibiotic or class of antibiotics with that specific isolate. Once the zone of inhibition has been measured in millimeters, it is compared with the Clinical Laboratory Standards Institute's (CLSI) guidelines for interpretation.<sup>1</sup> AST by disk diffusion is reported in one of three ways: (1) susceptible, indicating that the antimicrobial agent may be effective against the identified pathogen; (2) intermediate, indicating that the antimicrobial agent may be less effective than an antimicrobial agent with a susceptible result, that the organism may become resistant, or an antimicrobial agent may potentially be used if a high drug concentration is administered; or (3) resistant, a result indicating that the antimicrobial agent should not be used for therapy.

## BROTH DILUTION ANTIMICROBIAL SUSCEPTIBILITY TESTING

Broth dilution test methods are used to determine the least amount of antibiotic necessary to inhibit growth of the organism or the minimal inhibitory concentration (MIC). This method uses replicate inoculation of a standardized suspension of bacteria in broth into a series of micro-wells containing antibiotics in descending concentration expressed in micrograms per milliliter ( $\mu\text{g/mL}$ ). After a period of incubation, the wells are examined for bacterial growth (seen as turbidity). The first well in the series that shows no bacterial growth contains the minimum inhibitory concentration of the antibiotic that is effective against the organism being tested. Broth dilution test results are reported in micrograms per milliliter. The reading is compared with set breakpoints determined by CLSI for interpretation as sensitive, intermediate, or resistant.

Broth dilution AST can be conducted and read manually; however, most laboratories use some type of automated or computer-assisted instrumentation. In an automated system, the instrument actually reads the test results; in a computer-assisted system, a technologist visually assesses bacterial growth and records the results. Both systems generate interpretive criteria and cumulative susceptibility profiles. Although most instruments require overnight incubation of the test trays, some of the newer systems read growth photometrically and can generate results in as little as 3 to 10 hours.

## E-TEST

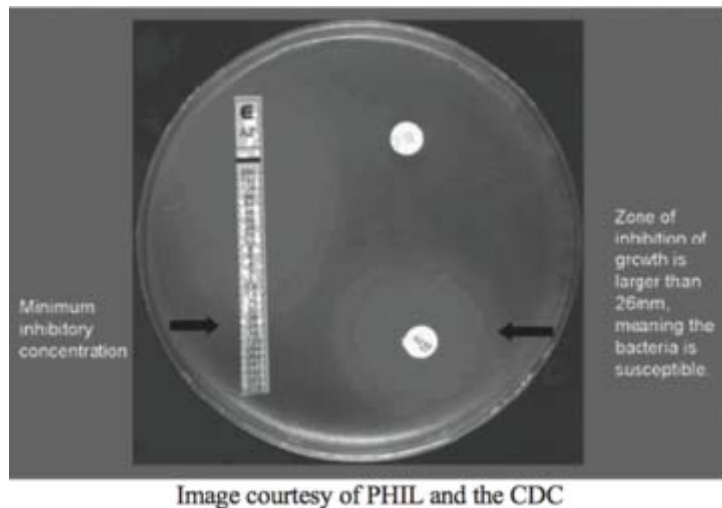
The E-test was developed to combine the ease and flexibility of disk diffusion with the ability to quantify resistance provided by broth dilution. In this method, a standardized suspension of bacteria is spread in a lawn fashion onto an agar plate. One or more nonporous plastic strips, impregnated with a serial dilution of a selected antimicrobial agent and marked with a MIC reading scale, are applied to the agar. The plate is then incubated overnight. After incubation, the plate is examined and the number at the point at which the border of the growth inhibition intersects the E-strip (at the meniscus) represents the

MIC (Figure 24-4). The same MIC interpretive criteria are used for E-tests and broth dilutions. E-tests are often used when the level of resistance can be clinically important (e.g., penicillin or cephalosporins against *Streptococcus pneumoniae*) with results reported in micrograms per milliliter. This test method is limited to certain antibiotics and is typically used for penicillin, ampicillin, and vancomycin.

## SPECIAL TEST METHODS

### B-LACTAMASE TEST

The  $\beta$ -lactamase test is designed to rapidly detect an enzyme produced by bacteria by which they may degrade antibiotics containing a chemical structure known as  $\beta$ -lactam. Organisms such as *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Staphylococcus* spp., and *Pseudomonas* spp. can be tested for  $\beta$ -lactamase production.



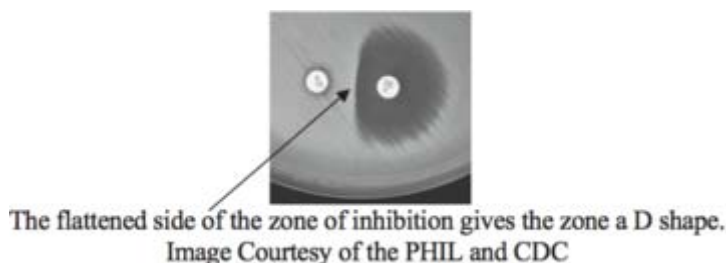
**Figure 24-4.**

E-test and disk diffusion. (Image courtesy of the Public Health Image Library and the CDC) [View Image](#)

### DISK APPROXIMATION TEST

In recent years, inducible clindamycin resistance has been observed in some *Staphylococcus* spp. These isolates test resistant to erythromycin and susceptible to clindamycin using routine AST methods. The presence of the "erm" gene in some strains of *Staphylococcus* induces production of the enzyme methylase, which allows clindamycin resistance to be expressed. In order to test for this inducible clindamycin

resistance, a simple disk approximation test, commonly referred to as the "D test," can be performed. An erythromycin disk is placed 15 to 26 mm (edge to edge) from a clindamycin disk in a standard disk diffusion test. After incubation, a flattening of the zone (Figure 24-5) in the area between the disks where both drugs have diffused indicates that the organism has inducible clindamycin



**Figure 24-5.**

D test for inducible clindamycin resistance. The flattened side of the zone of inhibition gives the zone a D shape. (Image courtesy of the Public Health Image Library and the CDC) [View Image](#)

Reporting clindamycin as susceptible for *Staphylococcus* spp. that test erythromycin-

resistant and clindamycin-susceptible without checking for inducible clindamycin resistance may result in inappropriate clindamycin therapy. The test described is acceptable for all *Staphylococcus* spp., including oxacillin-susceptible or oxacillin-resistant *S. aureus* or coagulase-negative staphylococci.

### MISCELLANEOUS TESTING

Synergy testing, which is used to determine the inhibitory ability of combinations of antibiotics, is often used with *Enterococcus* spp. and *Staphylococcus* spp. The Hodge test is used to detect the presence of



extended spectrum  $\beta$ -lactamase (ESBL) resistance in Gram-negative organisms (e.g., *Klebsiella pneumoniae*, *E. coli*, *P. aeruginosa*). This disk diffusion-based test has been modified to detect other enzyme-related (e.g., metallo- $\beta$ -lactamase, carbapenemase, and Amp C  $\beta$ -lactamase) antimicrobial resistance-producing strains of Gram-negative organisms. Minimal bactericidal concentration (MBC) test methods are used to determine minimal concentration of antibiotic necessary to kill (not merely inhibit growth of) an organism. Although MBC testing is infrequently performed, it may be helpful in certain clinical situations. Susceptibility testing is not commonly conducted for anaerobic organisms. If testing is required, MIC agar-based or broth dilution techniques may be used. Likewise, susceptibility testing for viruses and fungi is generally performed in reference laboratories and often is not standardized.

## RESISTANCE OF BACTERIA TO ANTIBIOTICS<sub>8</sub>

There are a number of kinds of mechanisms that would render bacteria resistant to antibiotics; (see Table 24-2). The mechanisms could be encoded in the cell's own genes or be obtained by acquisition of new genes by horizontal gene transfer (conjugation, transduction, transformation). The mechanisms include the following:

1. Inactivation of the antibiotic; for example, some bacteria can produce  $\beta$ -lactamase, an enzyme that catalyzes breakdown of antibiotics having a  $\beta$ -lactam chemical structure (penicillin includes a  $\beta$ -lactam structure);
2. Low permeability of the bacteria to the antibiotic;
3. Pumping antibiotics out of the cell after they have entered;
4. Low binding affinity of antibiotics for the bacterium; for example, mutations of a gene of *S. aureus* change some *Staphylococcus* proteins so that they cannot bind penicillin.

**Table 24-2** Examples of Organisms with  $\beta$ -lactamase Resistance

Resistant Mechanism	Organism	Antibiotic Effected
Enzyme alters antibiotic	<i>Staphylococcus</i> spp.	Penicillins
	<i>Pseudomonas aeruginosa</i>	Penicillins, cephalosporins, and aztreonam
Altered target	<i>Staphylococcus</i> spp.	Methicillin and other beta-lactam agents
	<i>Streptococcus pneumoniae</i>	Penicillin and cephalosporin
Decreased uptake	<i>Pseudomonas aeruginosa</i>	Imipenem

## SPECIMEN COLLECTION AND TRANSPORT<sub>8</sub>

Specimen collection and transport to the laboratory is an essential part of the culture and identification process. Improperly selected, collected, or transported specimens can generate misleading data that may result in inappropriate patient management. Consequently, improper specimen collection and transport is a reason for specimen rejection. In general, all specimens should be collected aseptically and placed in a sterile container. In some cases, specimens may be placed directly into culture media (e.g., blood cultures, genital cultures). Special handling techniques may be necessary for some specimens, such as those for anaerobic culture. Prompt delivery to the laboratory is essential to prevent the death of pathogenic organisms and/or the overgrowth of commensal organisms. If transport is delayed, some specimens may be refrigerated (e.g., urine, stool, sputum), whereas others should be maintained at room temperature (see Table 24-3).

**Table 24-3. General Guidelines for Collection of Optimum Specimens**<sup>15</sup>**Table 24-3** General Guidelines for Collection of Optimum Specimens

1. Collect the material from the site in which the etiologic agent will most likely be found.
2. Collect the specimen at the optimum time (e.g., early morning sputum for acid-fast bacillus [AFB]).
3. Obtain cultures prior to administration of antibiotics whenever possible.
4. Collect adequate volume of material. Inadequate amounts of specimen may yield false-negative results.
5. Collect specimen in a manner that minimizes or eliminates contamination from indigenous flora as possible to ensure that the sample will be representative of the infected site.
6. Use appropriate collection devices, transport media, and sterile, leak-proof containers.
7. Use sterile equipment and aseptic technique to collect specimen to prevent introduction of microorganisms during invasive procedures.
8. Clearly label the specimen including specific information regarding site of collection (e.g., blood obtained via blue lumen of right subclavian central catheter) and complete the ordering process.
9. Identify the specimen source and/or specific site correctly so that proper processing methods and culture media will be selected by the laboratory personnel.
10. If the specimen is collected through intact skin, cleanse the skin first with 70 percent alcohol, and iodine solution (e.g., povidone-iodine), or chlorhexidine/alcohol combination. If iodine is used, remove excess iodine after the specimen has been collected.
11. Provide clear instructions to patients if they are collecting their own specimen (e.g., clean catch urine or stool) in order to obtain the best quality specimen and allay their fears.
12. Deliver the specimen promptly to the laboratory. Delay in transport may compromise the specimen.
13. As with all patient contact episodes, consistent attention must be given to hand hygiene and use of appropriate personal protective equipment.
14. Use appropriate safety devices to minimize risk of accidental needle stick, cut, or puncture. It is advisable to make sure the user is knowledgeable about how the safety device works prior to its use.

Specific procedures for specimen collection and transport are institution dependent; however, there are some general guidelines to facilitate collection of the optimum specimen for examination. Please refer to your institution's laboratory manual for specific procedures and protocols.

## Microbial Pathogenesis

### NORMAL FLORA AND COLONIZATION

<sup>8</sup>

Microorganisms are ubiquitous in nature and are naturally present in and on humans; the terms used for those found on healthy surfaces is normal flora or common commensals. Typical normal flora organisms vary by body site. The term colonization generally denotes the presence of a microorganism in the absence of symptoms or deep tissue invasion. Normal flora may be described as colonization in most cases (e.g., *E. coli* colonization of stool), whereas potentially pathogenic organisms may exist as

colonizers. Colonizing organisms (e.g., *N. gonorrhoeae* colonization of pharynx, *Salmonella* spp. colonization of stool, methicillin-resistant *S. aureus* colonization of the nares, yeast in genital tract) may facilitate transmission to others or may lead to disease in the colonized individual during a disruptive situation (e.g., normal flora out-of-balance from antimicrobial treatment, invasive device, or wound).<sup>4</sup> For a list of common commensals, see the APIC *Ready Reference for Microbes*, 3rd edition.

## INFECTION

The term *infection* refers to a condition in a host resulting from the presence and invasion of microorganisms. Infection implies either recovery of an organism from a normally sterile body site or the production of an inflammatory response to a microorganism. An asymptomatic infection occurs when viable organisms are present in a body site without causing any obvious symptoms (e.g., latent tuberculosis, chronic Hepatitis B, latent syphilis). The immune status of the host plays a large role in determining the likely pathogenic potential of a microorganism. Infections with organisms that cause disease primarily in immunodeficient hosts are called opportunistic infections (e.g., *C. neoformans* meningitis in patients with deficient cell-mediated immunity, *Legionella pneumophila* pneumonia in patients with chronic lung disease or transplant recipients). Although almost any organism can cause an infection if introduced into a normally sterile body site, certain organisms are commonly associated with specific types of infections as shown in Table 24-4.

**Table 24-4** Infections and Common Organisms

Infection / Site	Common Organisms	Less Common Organisms
Bronchitis	<i>S. pneumoniae</i> , <i>H. influenzae</i> , respiratory viruses	<i>B. pertussis</i> , RSV
Device-related	Coagulase-negative staphylococci, <i>Corynebacteriasp.</i>	Gram (–) bacilli, <i>Candidasp.</i>
Empyema	<i>S. aureus</i> , streptococci, anaerobes	<i>S. pyogenes</i> , <i>H. influenzae</i>
Endocarditis	<i>S. viridans</i> , <i>S. aureus</i> , enterococci	<i>Haemophilussp.</i> , <i>S. epidermidis</i> , <i>Candidasp.</i>
Gastroenteritis	<i>Salmonellasp.</i> , <i>Shigellasp.</i> , <i>Campylobactersp.</i> , <i>E. coli</i> O157:H7, viruses	<i>Giardiasp.</i> , <i>Yersiniasp.</i> , <i>Vibriosp.</i>
Meningitis	<i>H. influenzae</i> , <i>N. meningitidis</i> , <i>S. pneumoniae</i>	<i>L. monocytogenes</i> , <i>C. neoformans</i> , <i>M. tuberculosis</i> , <i>Pseudomonassp.</i> , <i>E. coli</i>
Pelvic inflammatory disease	<i>C. trachomatis</i> , <i>N. gonorrhoeae</i> , <i>Bacteroidessp.</i> , Enterobacteriaceae	
Peritonitis	<i>Bacteroidessp.</i> , anaerobic cocci, enterococci, Enterobacteriaceae	<i>S. aureus</i> , <i>Candidasp.</i>
Pharyngitis	<i>S. pyogenes</i> , respiratory viruses	<i>C. albicans</i> , <i>N. gonorrhoeae</i> , <i>C. diphtheriae</i>
Pneumonia (community)	<i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , <i>M. tuberculosis</i>	<i>S. aureus</i> , Gram-negative bacilli, anaerobes, <i>L. pneumophila</i> , <i>P. carinii</i>
Pneumonia (healthcare-associated)	<i>Pseudomonassp.</i> , <i>S. aureus</i> , Enterobacteriaceae	<i>Legionellasp.</i> , <i>S. pneumoniae</i>

Osteomyelitis	<i>S. aureus</i>	<i>Salmonellasp.</i> , <i>Pseudomonassp.</i> , <i>S. agalactiae</i>
Septic arthritis	<i>S. aureus</i> , <i>N. gonorrhoeae</i>	<i>S. pneumoniae</i> , <i>S. pyogenes</i>
Septicemia	<i>S. aureus</i> , <i>S. pneumoniae</i> , <i>E. coli</i> , <i>Klebsiellasp.</i> , <i>Salmonellasp.</i>	<i>Clostridiumsp.</i> , <i>Candidasp.</i> , <i>Listeriasp.</i>
Sinusitis	<i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>S. pyogenes</i> , <i>S. aureus</i>	Gram-negative bacilli
Skin	<i>S. aureus</i> , <i>S. pyogenes</i> , <i>Candidasp.</i> , dermatophytes	Gram-negative bacilli, <i>Clostridiumsp.</i>
Urinary tract	<i>E. coli</i> , enterococci, <i>Candidasp.</i> , <i>Klebsiellasp.</i> , <i>Proteussp.</i>	<i>Pseudomonassp.</i> , <i>S. saprophyticus</i>

Adapted from Brooks K. *Ready Reference for Microbes*, 3rd ed. Washington, DC: APIC, 2012. See the guides for a detailed list.

## SOURCES OF MICROORGANISMS

Microorganisms can come from a variety of sources. Exogenous organisms are those that come from outside of the person or host. Exogenous sources include other humans (e.g., herpes virus, *M. tuberculosis*), foodstuffs (e.g., *Salmonellasp.*), contaminated water sources (e.g., *Giardia*, *Enterovirus*), insects (e.g., Lyme disease, malaria), animals (e.g., *Brucellosis*, *Pasteurellasp.*), and airborne sources (e.g., *Histoplasma*, *Legionellasp.*). Endogenous organisms are derived from the host's own microbial flora (e.g., *S. aureus* carried on skin, *E. coli* carried on the perineum). For some organisms, the distinction is not clearcut; some pathogens may be acquired first as colonizers, only to cause disease later (e.g., *Pneumococcus* spp. acquired from another host first causes pharyngeal colonization and then subsequent pneumonia).

## The Role Of The Laboratory In Outbreak Investigation

Clinical laboratories play a pivotal role in both endemic and epidemic epidemiology, but the awareness is heightened during the investigation of an outbreak. Laboratories assist in the identification of an outbreak by confirming organism identities, recognizing organism clusters, and detecting unusual organisms and antimicrobial susceptibility patterns. Additionally, they retrieve and review archival data to determine background rates of organism isolation and help determine if an outbreak situation actually exists. Finally, laboratories can save microbes isolated from suspected cases and assist in testing to determine if the microbes are the same or related.

It is essential that the infection preventionist coordinate closely with the laboratory team when planning for a potential outbreak. In some facilities, development of an interdisciplinary outbreak response team has been used, but this is not a requirement. However the organization response is structured, the readiness of the infection prevention staff and the laboratory is critically important in the execution of a timely and robust containment plan.

## Environmental Testing

Microbiological environmental testing is not generally recommended. Environmental culturing can be costly and may require special laboratory procedures. Additionally, in most cases, no standards for comparison exist. Because of the lack of standards, environmental testing may generate inconclusive data that could result in the implementation of unnecessary procedures or treatment. Rationale for special environmental monitoring should be carefully planned and limited to epidemiological investigations. In limited situations, "routine" environmental sampling may be indicated.

## ROUTINE ENVIRONMENTAL TESTING<sup>16</sup>

Routine microbiologic sampling for quality assurance purposes should be limited to: (1) biologic monitoring of sterilization processes; (2) monthly cultures and endotoxin testing of water and dialysate in hemodialysis units; and (3) short-term evaluation of the impact of infection prevention measures or changes in infection prevention protocols.

Biological monitoring of sterilization procedures is designed to provide a maximal challenge to the sterilizer to ensure that other items in the load are sterile without physically opening and culturing a number of items in the load. Standardized preparations of bacterial spores (biological indicators) are commercially available as self-contained indicator systems. Different bacterial spores and incubation temperatures are used to test different types of sterilizing procedures. (See **31. Cleaning, Disinfection, and Sterilization**, and **106 Sterile Processing**, for more details.)

Dialysate and water in hemodialysis units are tested to satisfy local regulations and/or national standards for water quality. These samples are typically tested monthly using standardized protocols and guidelines (see **39. Dialysis**, for more details). Short-term environmental sampling can be conducted to evaluate the effectiveness of infection prevention protocols. Examples of this type of testing are evaluating new cleaning procedures and/or products and for education of employees and staff members or water culturing after *Legionella* abatement.

## SPECIAL ENVIRONMENTAL TESTING<sup>16</sup>

Environmental testing may be indicated when epidemiological investigation suggests that a source or reservoir of microorganisms may exist. Testing may involve personnel, medical devices, air, water, food, and/or surfaces. The type of sampling depends on the causative organism, type of infection, and potential sources/reservoirs. Quantitative test methods (determines the amount of an organism present) should be used rather than qualitative methods (determines only if an organism is present).

A variety of methods can be used for solid surface test samples. Swab-rinse sampling uses a template to swab a standardized area. Sponge-rinse and wipe-rinse methods use sterile sponges or wipes rubbed over a large area. Rinse-sampling involves direct immersion of an item if it can be totally exposed to a rinse solution. Impression plating is a method in which the culture media is placed directly onto the surface being tested.

Liquid or water testing is generally more difficult to conduct than solid surface testing. There are typically fewer organisms present in liquids and they may be harder to culture. One quantitative test method is the agar spread plate, in which a known quantity of the fluid is spread on solid culture media. A second quantitative method is the membrane filter method, in which a standard volume of fluid is passed through a membrane filter and placed on a pad containing media. If tests are being conducted to detect *Legionella* spp., special culture media must be used because of the growth requirements of the organism. For more information about environmental testing for *Legionella* spp., see **84. Legionella pneumophila**.



Fungal spores are ubiquitous in the environment and generally cause no harm to normal hosts; therefore, air sampling without reason is not recommended (refer to **23. The Immunocompromised Host**; **114 Heating, Ventilation, and Air Conditioning**; and **115 Water Systems Issues and Prevention of Waterborne Infectious Diseases in Healthcare Facilities**). There are no recommendations regarding routine microbiological air sampling before, during, or after construction or renovations (refer to ). The United States Pharmacopeia (USP) addresses air quality and systematic testing in pharmacies or compounding areas. Due to disease outbreak linked to compounding practices, federal legislation enacted in 2013, referred to as the Compounding Quality Act, is being implemented by the U.S. Food and Drug Administration. Although infection preventionists are not directly involved in the preparation of compounded medications, collaboration will most likely be needed to verify that environmental risks associated with sterile procedures and related equipment are being monitored and addressed as needed (refer to **110. Pharmacy Services**).

## Biosafety In Microbiological And Biomedical Laboratories

In 1969, the Centers for Disease Control and Prevention's (CDC) booklet *Classification of Etiologic Agents on the Basis of Hazard* detailed the code of practice for biosafety. Although the intent of the document was originally advisory, some regulatory agencies have made adherence mandatory. The principles of biosafety are based on containment and risk assessment. Containment refers to those employee or microbiological practices; selection, provision, and use of safety equipment; and facility safeguards that protect laboratory personnel, the environment, patients, and visitors from exposure to infectious microorganisms collected, processed, stored, and disposed of by the facility. In order to prevent laboratory-associated infections, a risk assessment is required to identify appropriate microbiological practices, safety equipment, and facility safeguards. For a detailed discussion of laboratory biosafety issues, see **25. Laboratory Testing and Diagnostics**.

## Future Trends

Clinical microbiology plays an important role in the practice of infection prevention as well as epidemiology. The many advances in molecular microbiology continue to provide new avenues of microbe detection and identification. For example, the identification of the mechanisms causing antimicrobial resistance will require the adaptation or modification of current tests, as well as development of new testing methodologies. As the public health threats associated with antimicrobial resistance continue to rise, infection preventionists can expect to see even wider engagement of the laboratories as optimum strategies and tactics to address these threats are identified and tested in clinical settings.

As research uncovers more information about the human microbiome, new opportunities will be recognized for the study of these organisms both for the maintenance of health as well as the incidence of disease. While advances have been made in understanding the human microbiome, much remains to be learned, especially in areas such as the intestinal tract where the microbiota have traditionally been extremely difficult to culture, and thereby study, in the laboratory.

Other future trends are equally as compelling. Research into the complexity of bacterial biofilms is needed to support efforts to eliminate healthcare-associated infections. The lean managed laboratories of the future will need to address the demands for cost containment not only for supplies and equipment but also to balance the demands for rapid/complex diagnostic testing with a well-educated and

technically prepared workforce. A current reflection of this emerging trend is the expansion of rapid and point of care testing procedures. As research into cost effective, timely, and accurate testing methods evolves, laboratories must also remain alert of the ever present threat of emerging pathogens. Coordination with local and state health officials, as well as the CDC, will remain, as it does today, a critical factor in the recognition and response to any communicable disease threat.

## International Perspective

The epidemiology and incidence of specific microorganisms can vary widely depending on the environment, commensal flora, and transmission risks. Organisms that may be common in one geographic area may be uncommon in another. However, given the ease of international travel, few microorganisms are "confined" to specific countries or areas and the possibility of a regional disease escalating into a pandemic threat has been well-documented not only for influenza, but for other infection diseases as well. Fortunately, today, laboratory techniques are similar in most parts of the world and technology makes information sharing possible in most areas.

Additionally, international agencies, such as the CDC and the World Health Organization, assist with laboratory analysis of unusual or epidemiologically important pathogens. Clinical microbiology laboratories must work closely with clinicians when unusual pathogens are detected and pandemic threats identified; see also **120. Infectious Disease Disasters: Bioterrorism, Emerging Infections, and Pandemics.**

## Supplemental Resources

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## Laboratory Testing and Diagnostics

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### Abstract

*When a patient is being evaluated for infection, a thorough history and physical examination, microbiological assessment, and other diagnostic tests usually are required. In addition to microbiological evaluations, the clinical laboratory can provide other diagnostic measurements that may help to diagnose/identify the infection or to evaluate the stage of an infectious disease or process. This chapter discusses laboratory test methodologies used in the detection, treatment, interpretation, and monitoring of infections. Although this chapter is not all-inclusive, it will offer the infection preventionist a better understanding of the type and scope of testing that is available from the clinical laboratory.*

### Key Concepts

- Laboratory procedures can be useful tools in the diagnosis of infection.
- Laboratory procedures can be used to assess the stage of infection or infectious process.
- Laboratory tests can be helpful in evaluating for healthcare-associated infections.
- Laboratory test accuracy and precision are key elements in selection and implementation of a test method.

### Background

The clinical laboratory can undertake microbiological evaluations and also can provide other diagnostic measurements to assist in the diagnosis and identification of infection or evaluate the stage of an infectious disease or process. Although recovery of the agent in culture is still the gold standard for identification of an infectious disease, the use of antigen (Ag) and antibody (Ab) reaction to identify the disease state has become common practice. The current trend is toward the detection of the antigen

more so than the antibody, and the use of nonculture methods allows for testing by nonlaboratory personnel and expanded testing in the clinic or ambulatory care setting. Additionally, the use of molecular methods is growing substantially, reducing the time to identification and, ultimately, diagnosis and appropriate treatment.

## Basic Principles

### ACCURACY

Accuracy is the closeness of the result obtained to the true value and is described by two terms: sensitivity and specificity. Sensitivity is the ability of a test to detect all true cases of the disease or the absence of false-negative results, whereas specificity describes the ability of a test to correctly identify a negative result when the disease is absent or the absence of the false-positive results.<sup>1</sup> Sensitivity is the number of true-positive results over the number of true-positive plus false-negative results. Specificity is the number of true-negative results over the number of true-negatives plus false-positive results. Both proportions are expressed as a percentage.

An example of sensitivity and specificity is seen with the use of the rapid protein reagin (RPR), a screen for *Treponema pallidum*, the causative agent for syphilis. The RPR test detects nonspecific antibodies that indicate the presence of *T. pallidum*; however, the test may produce false-positive results in the presence of viral infections (e.g., Epstein-Barr, varicella, hepatitis). If the RPR is positive, confirmation is performed with a highly specific test, such as the *Treponema pallidum* hemagglutination assay (TPHA), fluorescent treponemal antibody absorption (FTA-ABS), or a CAPTIA syphilis-G, a treponema-specific immunoglobulin G (IgG) enzyme immunoassay (EIA).

### PRECISION

Precision, often called repeatability, is when repeat testing on the same sample(s) consistently provides the same or similar results. It is important to note that without accuracy, the test could consistently reproduce an incorrect value.<sup>2</sup>

#### PROFICIENCY TESTING PROGRAM

Although the level of precision and accuracy is distinctive to each test methodology, the laboratory's quality assurance/quality control and proficiency testing programs, as required by regulatory agencies (e.g., Clinical Laboratory Improvement Act [CLIA],<sup>3</sup> Centers for Medicare & Medicaid Services, The Joint Commission), monitor overall accuracy and precision of all regulated testing performed. Proficiency testing is an external evaluation of the quality of a laboratory's performance. Periodically the laboratory receives specimens or "unknowns" to evaluate as they would a routine patient specimen. Results are submitted, graded, and compared with the consensus answers from referee laboratories analyzing the same specimens.

#### PURPOSE OF TESTS

Common purposes for tests are as follows:

- Screening is used to identify a disease process in individuals without signs or symptoms in large patient populations. Generally, screening tests have high clinical sensitivity, but require confirmation due to low specificity.

- Confirmation is used after a positive screen to ensure accuracy of the result and confirm the presence of the condition.
- Diagnosis is used for the evaluation of persons suspected of having a given disease state or characteristic.

## DIAGNOSTIC TESTS

Definitive diagnosis of infectious diseases or processes can be accomplished in several ways:

- Determination of the presence of an infectious agent, a substance known to cause disease, by direct visualization of the agent in the patient's specimen (e.g., *Plasmodium falciparum*, the causative agent of malaria, in red blood cells); detecting antigens or genetic material specific for the agent (e.g., Hepatitis B surface antigen); or by recovering the agent in culture of the patient's specimen (e.g., wound, urine, blood, throat, sputum).
- Detecting in clinical specimens those specific product(s) resulting from a specific infectious agent (e.g., *Clostridium difficile* toxin in feces).
- Detecting an immunological response (Ag-Ab reaction) specific to the infecting agent in the patient's serum (e.g., Hepatitis B surface antibody).
- Detecting the presence of an infectious agent through nucleic acid hybridization and amplification techniques.

## Diagnostic Methodologies

### DIRECT EXAMINATION

#### GRAM STAIN

By far the most common procedure conducted to directly examine a clinical specimen for the presence of microorganisms (i.e., bacteria or fungus) is the Gram stain. This procedure, along with additional staining methods, is discussed in detail in **Chapter 24 Microbiology Basics**.

#### HISTOLOGY/CYTOLOGY

Histology is the study of the microscopic structure of tissues, whereas cytology is the study of the formation, structure, and function of cells. Histological or cytological procedures involve gross and microscopic evaluation of a specimen or tissue by a qualified pathologist. Special fixing or staining techniques may be used, depending on the suspected infectious process. Histological examination is useful for diagnosing infections with agents that are difficult or impossible to culture. The infectious agent may be seen directly in the specimen or indirectly as characteristic cell damage. Histological or cytological examination may be useful in the diagnosis of actinomycosis, chlamydia, cytomegalovirus, genital herpes, giardiasis, histoplasmosis, leprosy (Hansen's disease), lymphogranuloma venereum, and rubeola.

#### WET MOUNT

Wet mount is the microscopic examination of fresh clinical specimens. Specimens routinely collected for wet mount include sputum viewed for fungal elements; stool examined for larvae, adult worms, ovum, cysts, or parasites; cerebral spinal fluid for *Cryptococcus neoformans*; vaginal secretions for *Trichomonas vaginalis*; and urine sediment for white blood cells (WBCs), bacteria, yeast, and parasites

(e.g., *T. vaginalis*). Chemicals such as 10 percent potassium hydroxide (KOH), Lugol's iodine, and simple stains (e.g., calcofluor white, India ink, Loeffler's methylene blue) are often added to the wet mount to increase visibility of the infectious agent or to highlight cellular features of suspected infectious agents.

## DETECTION OF THE ANTIGEN/ANTIBODY REACTION

### ANTIGEN DETECTION

Antigens are molecular structures, usually proteins or polysaccharides, that are capable of stimulating the human immune system into the production of antibodies such as immunoglobulins. (Also see **Chapter 22 Microbial Pathogenicity and Host Response**.) Antigens are not necessarily limited to infectious agents but include tumor cells, transplanted tissue, transfused cells, pollen, and other foreign substances. Antigen detection is a direct method to test for the presence of infectious agents (i.e., antigens). These tests differ from direct specimen examination in that they generally incorporate the use of immunologic or serologic procedures. These tests may be helpful in early diagnosis, when cultures are not yet positive or are not possible or practical. Methods are designed to detect the entire agent (e.g., virus) or part of the agent (e.g., bacterial cell wall structures). Several test methods may be used for antigen detection, including agglutination tests, immunofluorescence, and enzyme-linked immunosorbent assay (ELISA). Serum, body fluids, and other clinical specimens may be used for antigen testing.

**Table 25-1.** Properties of Human Immunoglobulins<sup>4</sup>

**Table 25-1** Properties of Human Immunoglobulins

	IgM	IgG	IgA	IgD	IgE
<b>Physiological Property</b>					
Normal adult serum					
Concentration (mg/mL)	1.2 to 4.0	8.0 to 16.0	0.4 to 2.2	0.03	17 to 450 ng/mL
Percentage of total immunoglobulin level	13	80	6	1	0.002
Synthetic rate (mg/kg/d)	2.2	35	24	0.4	0.003
<b>Biological Property</b>					
Agglutinating capacity	+4		+2	—	—
Homologous anaphylactic hypersensitivity	—		—	—	+4

Placental transport to fetus	—	—	—	—	—
<b>Other Properties</b>	Produced early in immune response; first effective defense against bacteremia; also found in secretions at mucosal surfaces and in breast milk	Combats microorganisms and their toxins in extravascular fluids	Defends external body surfaces	Present on lymphocyte surface of immunocompetent cells, important for B-cell activation or immunoregulation	Low levels in blood plasma; most found on tissue-based mast cells and basophils

Available antigen tests include, but are not limited to, adenovirus, bacterial meningitis (*Haemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, group B streptococcus), *Brucella* spp., *Cryptococcus* spp., Hepatitis B envelop, Hepatitis B surface, Hepatitis D, human immunodeficiency virus (HIV), influenza virus, *Legionella* spp., parainfluenza virus, *Cryptosporidium* spp., *Giardia lamblia*, *Entamoeba histolytica*, *Plasmodium* spp., *Wuchereria bancrofti*, *T. vaginalis*, and respiratory syncytial virus. (Also see specific chapters for more information on a number of these organisms; refer to index.)

### ANTIBODY DETECTION

An antibody, also known as an immunoglobulin, is produced against a foreign antigen by the B lymphocytes. The antibody attaches to the specific antigen/antigen product the individual's immune system created as a defense mechanism. Antibodies facilitate the body's removal of the agent; this process is referred to as humoral immunity. Once produced, antibodies circulate in the blood, secretions, or lymphatic fluid. There are five classes of antibodies, each with different properties and functions, as shown in Table 25-1. (See also **Chapter 22 Microbial Pathogenicity and Host Response**.)

Antibody detection is an indirect method of identifying infection by assessment of the host response (antibody production) to the invading microorganism; this sometimes is referred to as serology, serologies, or immunology testing. Results may be reported qualitatively (positive or negative) or quantitatively (titers) and should be interpreted in consideration of the predictive value of the specific test. A positive antibody titer does not necessarily indicate active infection but may represent a previous infection and should be considered accordingly. Several test methods are used for antibody detection, including agglutination tests, complement fixation, indirect immunofluorescent-antibody (IFA), immunoblot, indirect hemagglutination (IHA), bentonite flocculation (BF), and radioimmunoassay (RIA). (See Table 25-2.) Serum is the specimen typically tested; however, other specimens may be acceptable, depending on the suspected agent.

**Table 25-2** Antigen (Ag)/Antibody (Ab) Reaction-based Detection Methodologies

Test	Detection Methodology
Chemiluminescent immunoassay (CL-EIA)	Uses the same principle as the EIA except the label is a chemical that produces light energy that can be measured
Countercurrent immunoelectrophoresis (CIE)	This modification of immunodiffusion applies an electrical current to increase the speed of the Ag/Ab reaction; an older method no longer frequently used
Enzyme immunoassay (EIA)	Uses an enzyme label to tag the antigen or the antibody in the Ag/Ab reaction; the enzyme remaining after washing the reaction catalyzes a substrate that results in a reaction that can be measured with a spectrophotometer



Enzyme-linked immunosorbent assay (ELISA)	This method tests antigen by adding antibodies that are bonded to enzymes; the enzymes are able to catalyze a colored reaction that can be measured
Immunofluorescent antibody (IFA)	Uses the same principle as the EIA except the label is a fluorophore that can be measured by photon counting
Immunodiffusion (ID)	Ag/Ab reactions precipitate and diffuse out through gel or agarose; a visible precipitin band or line forms at the point of optimal concentration; used for fungal exoantigens
Particle agglutination	Artificial carrier particles (e.g., latex particle, polystyrene bead) coated with a known antibody are mixed with the specimen. The test is read by the presence or absence of visible agglutination (clumping) when the antigen is present. This methodology can also be used with known antigen-treated carrier particles to detect antibodies and treated animal red blood cells for hemagglutination reactions. Used for detection of bacteria (e.g., <i>Haemophilus influenzae</i> , group B streptococcus)
Radioimmunoassay (RIA)	Uses radioactive isotopes to label the antigen or antibody in the Ag/Ab reaction; the amount of isotope remaining after the reaction is washed is measured

A multitude of antibody tests exist for detection of infection or exposure to infectious agents. (Refer to Table 25-2.) Available antibody assays include, but are not limited to, adenovirus, chlamydia group, coxsackievirus, *Cryptococcus* spp., cytomegalovirus, Echinococcus, encephalitis viruses (e.g., California, eastern equine, St. Louis, Venezuelan, western equine, West Nile), Epstein-Barr virus, *Entamoeba histolytica*, select fungi, *Giardia* spp., *Helicobacter pylori*, Hepatitis A, Hepatitis B core, Hepatitis B envelope, Hepatitis B surface, Hepatitis C, Hepatitis D, herpes simplex, histoplasma, HIV, *Legionella* spp., Lyme disease, mumps, *Pneumocystis jiroveci*, poliomyelitis, psittacosis, rabies, Rocky Mountain spotted fever, rubella, rubeola, *Salmonella* spp., teichoic acid (a macromolecule present on the cell wall of Gram-positive organisms), toxoplasma, Treponema (syphilis), varicella zoster, and *Yersinia enterocolitica*. (Also see specific chapters for more information on a number of these organisms; refer to the index.)

Table 25-2 provides examples of the test methodologies available to detect the antigen/antibody reaction. To learn more about immunoassay and immunochemistry testing, please refer to the Supplemental Resources listed at the end of this chapter.

## MOLECULAR DIAGNOSTIC TESTING

Molecular testing has had a positive effect on the diagnosis of infectious diseases. The polymerase chain reaction (PCR) was the first test developed using a nucleic acid amplification method and is the most widely used. Other nucleic acid amplification tests are based on target, probe, or signal amplification methods. All molecular diagnostic tests are subject to false-positive results because they are sensitive to contamination from previous amplification testing; however, new laboratory designs and changes in practice and workflow have been implemented to decrease the risk of false-positive reactions.

### TARGET AMPLIFICATION METHODS

The target amplification methods include PCR, transcription-based amplification, and strand displacement amplification. These methods use enzyme(s) synthesis to create copies of the target nucleic acid by the following three steps: denaturation, annealing, and extension. Theoretically, at the completion of one cycle of these steps, the PCR products have doubled. The copies of the nucleic acid are labeled with a chemiluminescent marker, a radioactive marker, or an enzyme marker that can then be quantified.

### PROBE AMPLIFICATION METHODS

The probe amplification methods (e.g., ligase amplification reaction, cleavase/invader technology) differ from target amplification in that the probe amplification products contain a sequence present only in the initial probe(s). The enzyme produces a ligated product that serves as a template for amplification. This method uses three steps (denaturation, annealing, and ligation), which result in accumulation of amplified product that is subsequently bound by a detection antibody. The antibody is then labeled with fluorogenic substrate that can be quantified.

*SIGNAL AMPLIFICATION METHODS*

Unlike the target and probe amplification methods, in the signal amplification methods (i.e., branched DNA and hybrid capture assay) the concentration of the target nucleic acid is not increased. The test is based on increasing the concentration of label molecules attached to the nucleic acid. Enhanced target detection has been accomplished by the use of multiple enzymes, multiple probes, multiple layers of probes, and reduced background noise. Signal amplification has reduced false-positive results from cross contamination because the number of target molecules is not altered; consequently, the signal is directly proportional to the amount of target sequence present in the original specimen.

TESTS FOR INFECTIOUS PROCESS

A variety of tests other than microbial, serological, and molecular assays can be used to assess the body's response to infectious agents. Although most of these tests are not used specifically for diagnosis of infection, they may be useful in many cases. Some of the more commonly used tests are described here. See Supplemental Resources listed at the end of the chapter or contact your clinical laboratory professional for information on additional tests.

*BODY FLUID ANALYSIS*

When infection is suspected in a sterile body fluid (e.g., pleural fluid, peritoneal fluid, synovial fluid), a sample of the fluid is obtained using sterile technique for analysis of its various components and for the detection of the presence of abnormal constituents that may indicate infection. Appropriate collection of body fluids for analysis may include the use of a sterile anticoagulant because cells or bacteria present in the fluid can become trapped in clot formations, which could result in inaccurate results. The analysis usually includes total protein, specific gravity, cell count (red and white blood cells) with differential (types of WBCs present), body fluid glucose, Gram stain, and culture. Microscopic examination for crystals also may be requested. Because each body fluid has different "normal" levels, analysis results must be compared with the normal values for that fluid. However, in general, the presence of a large number of white blood cells in any body fluid is an indicator of infection or acute inflammation.

*CEREBROSPINAL FLUID ANALYSIS*

When meningitis is suspected, it is common practice to collect a specimen of cerebrospinal fluid (CSF) for analysis. Although CSF can be analyzed for a number of components (e.g., calcium, sodium, uric acid) for the diagnosis of infection, four basic components are considered: color and clarity, protein, glucose, and WBCs, including differential. The recommended method for performance of the differential cell count is cytocentrifugation because it allows Wright's staining of air-dried cytopspins and has good cell yield and good preservation of cells. Analysis results will vary depending on the type of infectious agent and may assist in early identification of the suspected pathogen. (See Table 25-3.)

Table 25-3 Findings in Cerebrospinal Fluid Analysis for Meningitis

Reference Values4
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Component	Adult	Neonate	Bacterial Infection	Viral Infection	Fungal Infection
Color/clarity	Clear/colorless		Cloudy	Clear/hazy	Clear/hazy
Protein (mg/dL)	15 to 45	115 to 170	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
Glucose (mg/dL)	50 to 80	60 percent of plasma value	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
WBC count					
Agglutinating capacity	0 to 5	0 to 30	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
WBC differential					
Lymphocytes	62 to 34	20 to 18	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
Monocytes	36 to 20	72 to 22	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
Neutrophils	2 to 5	3 to 5	Varies with patient and agent	Varies with patient and agent	Varies with patient and agent
Eosinophils	Rare	Rare	Rare	Rare	Rare

### COLD AGGLUTININS

Cold agglutinins are antibodies that cause clumping or agglutination of type O red blood cells at cold temperatures. The cold agglutinins test is used to detect antibodies that result from *Mycoplasma pneumoniae* infection or infectious mononucleosis. In combination with acute respiratory symptoms, a high cold agglutinin titer usually indicates *M. pneumoniae* infection, viral pneumonia, or primary atypical pneumonia.

### C-REACTIVE PROTEIN

C-reactive protein (CRP) is an abnormal serum glycoprotein produced by the liver during acute inflammation. It usually disappears rapidly when inflammation subsides, so its detection signifies the presence of a current inflammatory process. This analysis is sometimes used in the diagnosis of meningitis, pneumonia (pneumococcal), sepsis, tuberculosis, and urinary tract infection.

### LIVER FUNCTION TESTS

Liver function tests (LFTs) are groups of chemistry blood assays used to aid in the differential diagnosis of liver disease and injury. LFTs include tests for albumin, bilirubin, and ammonia levels. Additionally, LFTs commonly include tests to measure levels of several enzymes including alkaline phosphatase (ALP), gamma glutamyl transferase (GGT), and aspartate aminotransferase. Interpretation of these tests can help aid in the diagnosis of infectious processes such as chronic syphilis, subacute bacterial endocarditis, tuberculosis, and inflammation due to certain viral infections (e.g., Hepatitis B and Hepatitis C). Overall, these tests are used to detect the presence of liver disease, differentiate among different types of liver disorders, measure the extent of damage to the liver, and follow response to treatment.

### ARTERIAL BLOOD GAS

An arterial blood gas (ABG) is a test in which blood from an artery is taken and levels of arterial oxygen tension ( $P^aO_2$ ), carbon dioxide tension ( $P^aCO_2$ ), and acidity (pH) are measured. ABGs are used to determine gas exchange, which reflect gas exchange across the alveolar-capillary membrane in the lungs. Worsening gas exchange can indicate respiratory failure due to pneumonia which is inflammation of the lung usually caused by a bacterial or viral infection. This makes ABGs critical components in identifying healthcare-associated pneumonias and ventilator-associated pneumonias.

### *COMPLETE BLOOD COUNT*

The complete blood count (CBC) is a series of tests of the peripheral blood that evaluate different cellular components. The items commonly evaluated include hemoglobin, hematocrit, red blood cells (RBC), red blood cell indices, WBCs, WBC differential, platelets, and microscopic examination of stained blood smears. The CBC is used as a screening tool for general health assessment, as well as to track the progress of many diseases. However, for the purposes of diagnosing or monitoring infection, the WBC count and differential are most useful.

The WBC count is the total number of WBCs (leukocytes) in 1 mm<sup>3</sup> of peripheral blood. The WBC count has a wide range of normal values, depending on personal factors such as age. An increased WBC count (leukocytosis, WBC count >10,000) usually indicates infection, inflammation, or leukemic neoplasia. In some infections, especially sepsis, the WBC count can be extremely high and may reach levels associated with leukemia. This is called a "leukemoid" reaction. A decreased WBC count (leukopenia, WBC count <4,000) can occur in cases of overwhelming infection, acquired immunodeficiency syndrome (AIDS), viral hepatitis, mononucleosis, and legionnaires' disease.

The WBC differential count measures the percentage of each type of leukocyte present in the blood specimen. Five types of WBCs are found in the normal blood smear. In order of frequency, they are neutrophils, lymphocytes, monocytes, eosinophils, and basophils. The primary function of the neutrophil is phagocytosis. Acute bacterial infections stimulate neutrophil production and result in increased WBC counts. When production is stimulated, immature neutrophils, called band or stab cells, may enter the circulation from the bone marrow. This occurrence, referred to as "shift to the left" or "left shift," is indicative of an acute bacterial infection (e.g., appendicitis). Increased lymphocytes are associated with pertussis, syphilis, and toxoplasmosis. Lymphocytes with a characteristic frothy cytoplasm, called "atypical lymphs" or "reactive lymphs," are associated with a number of viral infections (e.g., cytomegalovirus, infectious mononucleosis). Increased monocytes are commonly associated with Epstein-Barr virus, tuberculosis, subacute bacterial endocarditis, syphilis, and protozoan rickettsial infections. Eosinophils, typically associated with allergic reactions, can be increased in parasitic infections and occasionally with leprosy, tuberculosis, systemic fungal infections, scarlet fever, and chlamydial pneumonia of infancy. Basophilia, an increase in basophils, is an uncommon finding but can be seen with food and drug allergies, variola and varicella infections, and ulcerative colitis.

### *COMPLETE BLOOD COUNT: ABSOLUTE NEUTROPHIL COUNT*

Neutrophils, as mentioned, are a type of WBC. They are referred to by various names, depending on locale: segmented neutrophils, segs, polymorphonuclear (PMN) leukocytes, or polys. In the WBC differential, neutrophils are expressed as a percentage observed in the total number of cells reviewed during the differential (standard is to count 100 cells). The absolute neutrophil count (ANC) is the total number of neutrophils in the blood. Neutropenia is the reduction of the ANC to approximately 1.5 to 2.0  $\times 10^9/L$ , whereas severe neutropenia or agranulocytosis is the reduction of the ANC to  $<0.5 \times 10^9/L$ . Patients with severe neutropenia (e.g., recent transplant patients, AIDS patients) are at high risk for infection.<sup>2</sup> The ANC can be calculated from the WBC count and the WBC differential; see Figure 25-1 for

an example. Some institutions use the ANC to determine if an immunocompromised patient should be placed in protective isolation.

**Case Study:** On Monday, June 15, a 6-year-old girl with a diagnosis of acute myeloid leukemia (AML), presented to the transplant unit to undergo allogeneic hematopoietic stem cell transplantation (HSCT) from a human leukocyte-antigen-matched family donor. On posttransplant day seven the physician ordered an ANC.

### LYMPHOCYTE SUBSET

The primary function of lymphocytes is to fight chronic bacterial infections and acute viral infections. Lymphocytes are divided into two types: T cells (mature in the thymus) and B cells (mature in the bone marrow). T cells are involved primarily with cellular-type immune reactions, whereas B cells participate in humoral immunity (antibody production). T cells are killer cells, CD8 are suppressor cells, and CD4 are helper cells. The differential count does not separate the type of lymphocyte, and further testing is necessary to quantify them in the blood. Of particular interest in monitoring the progression of HIV infection are the CD4 count, CD4 percentage, and the CD4/CD8 ratio. As the CD4 count decreases, the probability of developing AIDS increases. (See [Chapters 81 HIV/AIDS](#), and [22 Microbial Pathogenicity and Host Response](#).)

$$\text{ANC} = \text{Total WBC} \times \frac{(\text{Segs} + \text{Bands})}{100}$$

Total WBC: 400/mm<sup>3</sup>; segs, 75%; bands, 10%;

$$\text{ANC} = 400 \times \frac{(75 + 10)}{100} \text{ or } 400 \times 0.85.$$

ANC = 340 neutrophils/mm<sup>3</sup>, which places the patient at high risk for infection.

**Figure 25-1.**

Calculating an absolute neutrophil count

[View Image](#)



### SEDIMENTATION RATE

When a tube of well-mixed, anticoagulated, venous blood is positioned vertically, the RBCs or erythrocytes will tend to fall to the bottom. The rate at which they fall is referred to as the erythrocyte sedimentation rate (ESR). Although

this test lacks sensitivity and specificity for disease processes, it nevertheless is used frequently. An increased ESR is associated with several disease states, including acute infection and inflammation.

### FECAL LEUKOCYTES

Fecal leukocytes are used to help determine the type of diarrhea, invasive or noninvasive, to the mucosa of the colon. The presence of leukocytes in the stool indicates that the cause of diarrhea is an organism or process, such as *Salmonella*, *Shigella*, *Amoeba*, *Campylobacter*, *Helicobacter*, or *Yersinia* infection, that is breaking the mucosal barrier of the colon. Leukocytes are usually not present in infectious processes that do not invade the mucosa, such as viral enteritis or toxin-mediated diarrhea. *Clostridium difficile* may or may not be associated with leukocytes in the stool. (Also see specific chapters for more information on a number of these organisms; refer to the index.)

### TOXIN PRODUCTION TESTING

Some organisms produce toxins that are further classified as exotoxins or endotoxins. Exotoxins are proteins secreted by both Gram-negative and Gram-positive organisms (e.g., *Clostridium tetani*, *Corynebacterium diphtheriae*, *C. difficile*, *Staphylococcus aureus*). Many have an A/B motif, where A is the active portion and B is the binding portion of the toxin. Some properties of exotoxins include the ability to lyse host cells; alter the function of host cells, resulting in the death of the cell; and stimulate host T-cell responses that result in a cytokine cascade. Methods for the detection of exotoxins include



EIA and high-performance liquid chromatography (HPLC), also known as high-pressure liquid chromatography.

Endotoxins are the lipid A section of the lipopolysaccharides that are found only on the outer membrane of some Gram-negative organisms (e.g., *Escherichia coli*, *Salmonella*, *Shigella*, *Pseudomonas*, *Neisseria*, *H. influenzae*, *Bordetella pertussis*, *Vibrio cholerae*). Endotoxins cause damage to the host through cytokine production by macrophages. The most commonly used test for endotoxin is the limulus amoebocyte lysate (LAL) test, which can be performed using a variety of methods, including gel-clot, turbidimetric, and chromogenic measurement. Some LAL methods allow for qualitative and semiquantitative results. The LAL assay is also used to test water quality for hemodialysis (refer to **Chapter 39 Dialysis**).

### *WEIL-FELIX AGGLUTININ*

Weil-Felix agglutinin is a test performed to detect and differentiate rickettsial antibodies in the serum. A single high titer or a fourfold rise in titer between acute and convalescent samples is considered diagnostic. This test can be useful in diagnosing Rocky Mountain spotted fever, Q fever, epidemic typhus, murine typhus, scrub typhus, and rickettsialpox.

### *URINALYSIS*

Urinalysis is a frequently used screening test to assess general health, as well as the health of the urinary tract. In addition, a urinalysis screen is important in determining catheter-associated urinary tract infections. Total urinalysis involves multiple routine tests and typically includes assessment of color, clarity, and presence of proteins, glucose, ketones, blood, nitrite, and leukocyte esterase. In addition, the urine may be examined microscopically for the presence of RBCs, WBCs, casts, crystals, bacteria, or yeast. Of the many components tested, only a few are used to screen for infection. Dipsticks, which detect the presence of leukocyte esterase and nitrite in the urine, can be used as a screening tool for the presence of infection. A positive leukocyte esterase (LE) test indicates that leukocytes (WBCs) or debris from ruptured WBCs are present in the urine. A positive nitrite test is used to screen for the presence of bacteria in the urine because many bacteria produce an enzyme that can reduce urinary nitrates to nitrites. If nitrites are present in the urine, it may indicate that bacteria are present. Most studies have demonstrated diagnostic value of the nitrite and LE results, especially when they are in agreement. In cases of true infection, a significant number of leukocytes ( $>10$  WBC/mm<sup>3</sup> of unspun urine or  $>5$  WBC/high power field of spun urine) should also be present, called pyuria. Given the very high association between infection and pyuria, this test can be helpful in differentiating between colonization and true infection in the presence of bacteriuria. Finally, during microscopic evaluation, the specimen is also examined for the presence of bacteria or yeast. (See **Chapter 33 Urinary Tract Infection**.)

## Conclusions

The most common procedure for directly examining a clinical specimen for the presence of microorganisms (i.e., bacteria or fungus) is the Gram stain. Histological or cytological procedures, which involve gross and microscopic evaluation of a specimen or tissue by a qualified pathologist, are useful for diagnosing infections with agents that are difficult or impossible to culture. Antigen detection may be helpful in early diagnosis, when cultures are not yet positive or are not possible. Antibody detection does not necessarily indicate active infection but may indicate a previous infection or exposure to infectious agents. A variety of tests other than microbial assays can be used to assess the body's response to infectious agents.

There are a multitude of test methodologies and diagnostic assays available to evaluate clinical specimens. To better understand the process of test selection and implementation in your facility, contact the laboratory medical director, chief technologist, laboratory manager, or microbiology supervisor.

## Future Trends

Molecular diagnostic testing and the use of platform-based automation will affect the performance and cost of diagnostic testing. With the ability to target the specific product, cell type, antigen, or organism of concern, laboratory methods will provide increasing accuracy and decrease turnaround time. The development of rapid highly specific test methods to detect genetically altered organisms takes on greater significance with the advent of bioterrorism-based or weaponized microorganisms. In addition, it can aid in the identification of new strains and prevent the spread of more resistant, virulent microorganisms.

## International Perspective

Laboratory techniques are similar in most parts of the world, and testing is fairly standard. In addition, international agencies, such as the Centers for Disease Control and Prevention, can assist with laboratory analysis of unusual or epidemiologically important pathogens. Clinical microbiology laboratories must work closely with clinicians if unusual pathogens are suspected.

## Supplemental Resources

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## Feedback form

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## Antimicrobials and Resistance

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### Abstract

*Although infection prevention traditionally has approached the problem of resistance primarily from the aspect of preventing transmission, more needs to be done to control how antimicrobials are commonly used. Antimicrobial use is the main selective pressure responsible for the increasing drug resistance seen in hospitals. Patients come to possess a resistant pathogen by either having their bacteria acquire a gene that codes for resistance or by transmitting bacteria that already have the resistance gene in place. The former takes days to weeks to develop, whereas the latter merely requires a handshake. To have an impact on antimicrobial use so as to reduce resistance, infection preventionists need a working knowledge of available antimicrobials, principles for their appropriate use, the mechanisms by which these drugs inhibit microbial growth, and the mechanisms by which microorganisms develop resistance. In addition, infection preventionists need to understand promising new strategies to improve antimicrobial use and how members of the infection prevention community can become more involved.*

### Key Concepts

- Although infection prevention traditionally has approached the problem of resistance primarily from the aspect of preventing transmission, more needs to be done to control how antimicrobials are commonly used.
- Antimicrobial stewardship is the best investment for preventing the proliferation of multidrug-resistant pathogens and the adverse events associated with the drugs used to treat such pathogens.
- An antibiogram is a useful tool for infection preventionists to determine the status of strategies in place to reduce multidrug-resistant pathogens.

- A multidisciplinary approach involving infection preventionists; the departments of infectious diseases, microbiology, and pharmacy; and others is necessary to confront antimicrobial resistance issues in healthcare settings.

## Background

Epidemiological forces responsible for clinically important types of resistance include (1) the selective pressure produced by antimicrobial use and (2) the transmission of resistance between microbes and between or among their human and animal hosts. Although most resistance can be traced to the human behaviors that lie behind these forces, the development and spread of resistance also are greatly affected by certain microbial characteristics, such as the ease by which an organism can develop or acquire resistance traits. Infection prevention, by its very nature, traditionally has been concerned with preventing the transmission of resistant organisms between human hosts in the healthcare setting. This chapter discusses available human antimicrobial agents, how they are used, antimicrobial resistance, and the management of antimicrobial use as a means to control resistance.

This chapter reviews all major antimicrobial categories with special mention of agents that have been released since the last edition of this book. Characteristics and indications for use particularly for drugs commonly used among inpatients, the determination and interpretation of antimicrobial susceptibility test results, and various factors influencing successful antimicrobial therapy are reviewed. The chapter also reviews microbial mechanisms responsible for antimicrobial resistance and methods to monitor and improve antimicrobial use.

## Basic Principles

### CHARACTERISTICS OF ANTIMICROBIAL AGENTS

#### ***Definition***

An antimicrobial is a substance that inhibits or kills microbes (viruses, bacteria, fungi, parasites), whereas an antibiotic is a type of antimicrobial that is synthesized by a living microorganism, usually a fungus. Trimethoprim is technically an antimicrobial but not an antibiotic because a microorganism does not synthesize trimethoprim. Many newly marketed agents are chemically modified from products synthesized by a microorganism.

#### ***Administration***

Most antimicrobials are administered by intravenous (IV) or oral routes. Less common routes of administration include intramuscular, rectal, topical, intrathecal, intraventricular, inhalation, intraperitoneal, surgically implanted antimicrobial devices (e.g., orthopedic hardware or beads), and antimicrobial-coated devices (e.g., endotracheal tubes or urinary catheters).

#### ***Mechanisms of Action***

Antimicrobials may be bactericidal or fungicidal if they actively kill organisms, or they may be bacteriostatic or fungistatic if they merely arrest the growth of organisms and assist the host's immune system in clearing the infection. Whether a drug exerts "-cidal" versus "-static" activity can depend on the concentration to which an organism is exposed, but for most drugs the safely achieved concentrations in the human body are limited to a narrow enough range that this distinction is determined more by the underlying mechanism by which the drug inhibits microbial growth.

There are several mechanisms by which antimicrobials act on microorganisms (Table 26-1). All  $\beta$ -lactam drugs (e.g., penicillins, cephalosporins, monobactams, and carbapenems); the glycopeptide vancomycin; and the echinocandins (e.g., caspofungin) inhibit cell wall synthesis. Cell membrane inhibitors include daptomycin, colistimethate, and the imidazole antifungal agents, such as fluconazole, which inhibits an enzyme responsible for a crucial component of the cell membrane. Aminoglycosides (e.g., gentamicin and tobramycin), macrolides (e.g., azithromycin), tetracyclines, and the oxazolidinone, linezolid, all inhibit protein synthesis in the bacterial ribosome. Another mechanism inhibits the production of metabolites essential for cell function (e.g., trimethoprim-sulfamethoxazole and ethambutol). Finally, several drugs, including the fluoroquinolones (e.g., ciprofloxacin, levofloxacin, and moxifloxacin), the antifungal flucytosine, and many of the antivirals (e.g., acyclovir) inhibit nucleic acid synthesis.

Pharmacodynamic Factors

The effectiveness of antimicrobials can be optimized by understanding what effect varying the concentration of a drug over time in relation to the minimal inhibitory concentration (MIC) has on eliminating infection from the human body.<sup>1</sup>The MIC is the lowest concentration of drug that still can inhibit microbial growth. The logical assumption would be that for all drugs you would want to keep the concentration of the drug in the blood above the MIC at all times.

Table 26-1 Major Cellular Sites of Action by Antimicrobial Classes

Site of Mechanism of Action	Antimicrobial
Cell wall	$\beta$ -lactam (penicillin)
	Vancomycin
	Echinocandin
Cell membrane	Cyclic lipopeptide (daptomycin)
	Triazole (fluconazole)
Ribosome	Macrolide
	Aminoglycoside
	Linezolid
	Tetracycline
Nucleic acid synthesis	Fluoroquinolones
	Antiviral (acyclovir)
	5-Flucytosine
Metabolic pathway	Trimethoprim-sulfamethoxazole
	Ethambutol

In order to explain why this is not the case for every antimicrobial, the concept of half-life should be understood. Half-life is a term used to quantify how long the body takes to metabolize half of a drug, an

antimicrobial in this case. Drugs such as aminoglycosides and fluoroquinolones are said to manifest *concentration-dependent activity*. In the case of these drugs, achieving a higher concentration in the blood over a short time is thought to be more effective at eliminating infection than maintaining a lower concentration over a longer period (Figure 26-1). One characteristic of these drugs is that they usually have a prolonged post-antibiotic effect; that is, they continue to suppress microbial growth long after drug concentration has declined. The goal with these drugs is to maximize serum or tissue drug concentrations, which often allows for once-daily dosing.

In contrast, the activity of the  $\beta$ -lactams depends on maintaining drug concentrations in the body above the MIC. Drugs that have such *time-dependent (above the MIC) activity* are best dosed with lower doses at an increased frequency (Figure 26-2). This understanding has led to drugs such as the natural penicillins and ampicillin being increasingly dosed as a continuous infusion, rather than less frequent dosing, in the management of serious infection. Notice that in Figure 26-1, there is a longer period of time between the end of the half-life and the next dose of the concentration-dependent drug compared to the time-dependent drug in Figure 26-2. Also notice that the concentration curve in Figure 26-1 goes below that MIC level while it stays above the level in Figure 26-2.

### Side Effects

Two major types of side effects are allergic and gastrointestinal reactions. Allergic reactions, including those manifested by rash, fever, and rare anaphylaxis, are undesirable effects that may occur with virtually any antimicrobial. Common gastrointestinal disturbances include nausea and vomiting and, because virtually all antimicrobials inhibit microbial growth in the large intestine, diarrhea. Most antibiotic-associated diarrhea is benign and resolves with cessation of the drug, but suppression of the anaerobic bacteria of the colon predisposes to infection with *Clostridium difficile*. The current *C. difficile* epidemic strain can cause life-threatening colitis, especially if due to the BI/NAP1/027 strain. Other forms of superinfection resulting from the suppression of normal microbial flora include vaginal candidiasis and oral thrush. Other types of toxicities and their most common manifestations include hepatotoxicity, manifested as elevation of liver enzymes (which is often asymptomatic); myelosuppression, manifested as leukopenia or thrombocytopenia; renal toxicity, manifested as progressive decline in renal function or electrolyte abnormalities; auditory toxicity, manifested as high-frequency hearing loss; vestibular toxicity, manifested as dizziness or vertigo; and central nervous system toxicity, manifested as change in mental status or seizure. Because they often go unrecognized, drug-drug interactions may be particularly prone to cause serious toxicity.

### Figure 26-1.

Optimal dosing of antimicrobial drugs possessing concentration-dependent killing action.

[View Image](#)

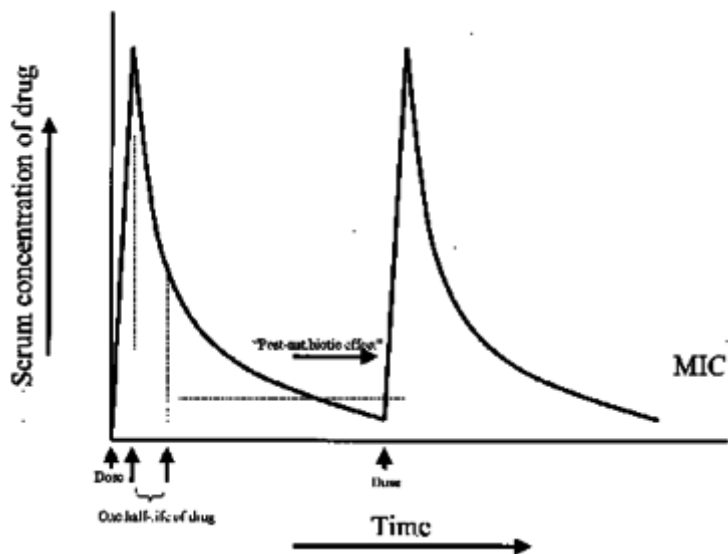


## Classification and Review of Commonly Used Drugs

The major classification of antimicrobials is based on the broad category of microorganisms against which the drugs possess activity; these include antibacterials (Table 26-2), antivirals (Table 26-3), antifungals (Table 26-4), and antiparasitics.

### ANTIBACTERIALS

#### Penicillins



mouth. Natural penicillin remains the drug of choice for the treatment of group A streptococcal pharyngitis and other infections caused by this pathogen, despite more than 50 years of use.

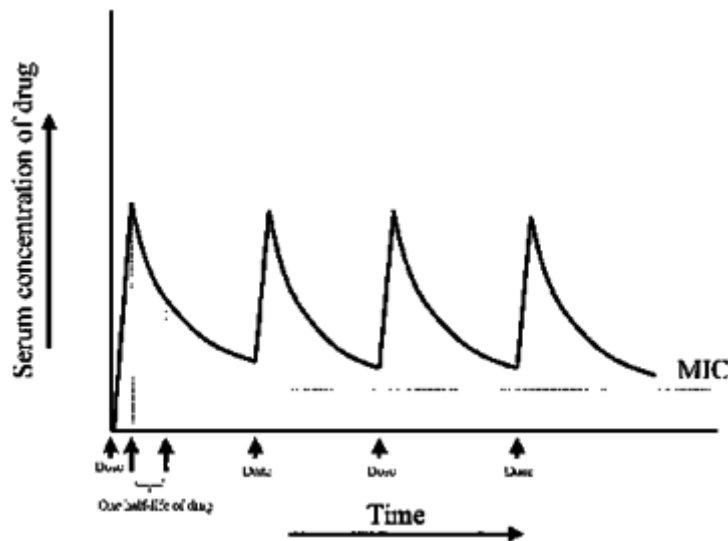


Figure 26-2.

Optimal dosing of antimicrobial drugs possessing time-dependent killin [View Image](#)

As a result of penicillin G's lack of activity against Gram-negative bacteria, the aminopenicillins, including ampicillin and amoxicillin, were developed. These drugs possess activity against Gram-negative organisms such as *Escherichia coli* and *Haemophilus influenzae*, while retaining all of the Gram-positive and anaerobic activity of the natural penicillins. In response to the rapid spread of penicillin-resistant staphylococci throughout the United States in the 1950s,

penicillinase-resistant penicillins were developed. The first of these, methicillin, was released in 1962 and now has been largely replaced by other penicillinase-resistant penicillins with less toxicity, such as nafcillin and oxacillin (IV) and dicloxacillin (oral). To combat the rising incidence of *Pseudomonas* infections in the late 1960s and 1970s, penicillins with antipseudomonal activity were developed, including piperacillin. Then,  $\beta$ -lactamase inhibitors were added to existing penicillins to inhibit bacterial enzymes from lysing the  $\beta$ -lactam chemical ring structure to broaden the activity of the base penicillin for three groups of pathogens: anaerobic bacteria, methicillin-susceptible but penicillin-resistant *Staphylococcus aureus* (MSSA), and Gram-negative bacteria. Currently used  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combinations include amoxicillin-clavulanate, ampicillin-sulbactam, and piperacillin-tazobactam.

Table 26-2 Classification of Antibacterials and Representative Drugs

Class	Subclass	Representative Drug
Penicillins	Natural penicillins	Penicillin G



Cephalosporins	First generation	Cefazolin
	Second generation	Cefuroxime
	Third generation	Ceftriaxone
	Fourth generation	Cefepime
	Fifth generation	Ceftobiprole
Other $\beta$ -lactams	$\beta$ -lactam/ $\beta$ -lactamase inhibitor	Piperacillin/tazobactam
	Monobactams	Aztreonam
	Carbapenems	Imipenem
Fluoroquinolones	Antipseudomonal	Ciprofloxacin
	Antistreptococcal	Moxifloxacin
Miscellaneous	Macrolides	Azithromycin
	Lincosamines	Clindamycin
	Aminoglycosides	Gentamicin
	Sulfa drugs	Trimethoprim/sulfamethoxazole
	Glycopeptides	Vancomycin
	Nitroimidazoles	Metronidazole
	Oxazolidinone	Linezolid
	Cyclic lipopeptide	Daptomycin
	Polymyxin	Colistin sulfate

**Table 26-3** Classification of Antivirals and Representative Drugs

Class	Subclass	Representative Drug(s)
Drugs for Herpesviridae	For herpes simplex	Acyclovir
	For cytomegalovirus	Ganciclovir
Drugs for influenza	For influenza A and B	Oseltamivir and zanamivir
Miscellaneous	For respiratory syncytial virus	Ribavirin
Antiretrovirals (drugs for HIV)	Nucleoside reverse transcriptase inhibitors	Emtricitabine
	Nonnucleoside reverse transcriptase inhibitors	Efavirenz
	Protease inhibitor	Atazanavir
	Fusion inhibitor	Enfuvirtide
	Entry inhibitor	Maraviroc
	Integrase inhibitor	Raltegravir

**Table 26-4** Classification of Antifungals and Representative Drugs

Class	Subclass	Representative Drug(s)
Polyenes	Nonlipid formulation	Amphotericin B
	Lipid formulations	Amphotec, Abelcet, and Ambisome
Azoles	Triazole	Fluconazole and voriconazole
Other	Echinocandin	Caspofungin
	Nucleoside analogue	Flucytosine

## Cephalosporins

Several generations of cephalosporins are available. The first-generation cephalosporins include cefazolin and cephalexin with activity primarily against Gram-positive bacteria, most *E. coli*, more than half of all *Klebsiella pneumoniae* at most institutions, and most strains of *Proteus mirabilis*. Second-generation drugs include cephalosporins with enhanced activity against *H. influenzae* (e.g., cefotaxime, cefuroxime) and cephalosporins with enhanced antianaerobic activity (e.g., cefoxitin). Both categories of second-generation cephalosporins possess increased activity against enteric Gram-negative bacilli and *Neisseriaspp.*

Third-generation cephalosporins (e.g., cefotaxime and ceftriaxone) have enhanced activity against Gram-negative bacilli. They achieve high blood concentrations and penetrate into relatively sequestered body sites, such as the central nervous system. Third-generation cephalosporins are important in the treatment of community-associated meningitis. However, penicillin and cephalosporin resistance among *Streptococcus pneumoniae* is increasing and may limit the usefulness of these drugs as empirical therapy. Although the antipseudomonal third-generation drug ceftazidime is important in the treatment of nosocomial meningitis due to Gram-negative bacilli, its use is discouraged because of its association with extended-spectrum  $\beta$ -lactamases.<sup>2</sup> Cefditoren is an oral agent with increased potency against *S. pneumoniae*, including strains that have only intermediate susceptibility to penicillin. Cefdinir has the benefits of being taken only once daily, having an oral suspension, and a similar spectrum of activity compared to other agents in the same class.

Cefepime, a fourth-generation cephalosporin, has broad-spectrum activity against Gram-negative bacteria, including *Pseudomonas spp.*, and Gram-positive bacteria. It is recommended by the Infectious Diseases Society of America for use in patients with neutropenia. However, cefepime covers neither methicillin-resistant *S. aureus* (MRSA) nor the anaerobic bacteria responsible for many lung, abdominal, and soft tissue infections. A review by the U.S. Food and Drug Administration (FDA) determined that data do not indicate a higher risk of death with cefepime.<sup>3</sup> Ceftaroline, the fifth-generation cephalosporin, has activity against MRSA and penicillin-resistant *S. pneumoniae*, *P. aeruginosa*, and Enterococci. It is intended for use in community-associated pneumonia and skin and soft tissue infections. Both cefepime and ceftaroline are intravenous antimicrobials.

## Miscellaneous $\beta$ -Lactams

There are two additional classes of  $\beta$ -lactam drugs: monobactams and carbapenems. Aztreonam is the only available monobactam and is unique among the  $\beta$ -lactam drugs in possessing a spectrum of antimicrobial activity limited only to aerobic, Gram-negative bacilli, including *P. aeruginosa*. It also is unique in that there is no allergic cross-reactivity between it and other  $\beta$ -lactam drugs, meaning that patients with a history of even serious reactions to penicillins or cephalosporins may be given aztreonam

safely. The carbapenems imipenem, meropenem, and doripenem are broad-spectrum agents with significant activity against a wide range of Gram-negative bacilli, including *Pseudomonas*, and are potent drugs in the treatment of serious infections involving anaerobic bacteria (e.g., intra-abdominal infections with sepsis). They possess activity against streptococci and staphylococci except for MRSA. Ertapenem has a spectrum of activity similar to that of other carbapenems except that it does not cover resistant Gram-negative bacilli, such as *P. aeruginosa* or *Acinetobacter*spp.

### Fluoroquinolones

Ciprofloxacin was the first highly potent fluoroquinolone; it still is used widely for the treatment of infections caused primarily by Gram-negative bacilli, including *P. aeruginosa*. Fluoroquinolones possess bactericidal activity by inhibiting the bacteria's DNA gyrase enzyme responsible for unwinding the chromosome during replication and cell division. Most of the available fluoroquinolones are limited in their activity against staphylococci and anaerobes, and ciprofloxacin has limited activity against streptococci. Levofloxacin and moxifloxacin were developed primarily for increased activity against *S. pneumoniae* for their use in the treatment of community-associated pneumonia. They also have important coverage against atypical pathogens such as legionella—a pathogen that may be acquired from a water source in or out of a hospital. In addition, levofloxacin covers *P. aeruginosa* (although resistance is increasing), whereas moxifloxacin covers anaerobic bacteria.

### Macrolides, Lincosamides, and Streptogramins

Azithromycin and clarithromycin have activity against Gram-positive bacteria and the atypical bacteria that cause pneumonia, such as *Legionella*, *Mycoplasma*, and *Chlamydia*spp. The macrolides and the closely related lincosamides and streptogramins (dalfopristin/quinupristin) inhibit 50S protein synthesis in the bacteria's ribosome. Because they are bacteriostatic and possess a limited spectrum of activity, macrolides are used most commonly to treat less serious community-associated infections. In addition to the treatment of upper and lower respiratory tract infections, macrolides (excluding erythromycin) have unique indications for the treatment of *Helicobacter pylori*-induced gastric and duodenal ulcers and infections due to nontuberculous mycobacteria.

Clindamycin is the principal lincosamide currently in use in the United States. Because clindamycin possesses activity against aerobic Gram-positive bacteria and anaerobic Gram-positive and Gram-negative bacteria, it historically has been used in the treatment of aspiration pneumonia and intra-abdominal infections. Its use has increased since the epidemic of community-associated MRSA strains, which commonly cause skin and soft tissue infections. Due to the possibility of treatment failures related to clindamycin-inducible resistance in some staphylococcal strains, a D-test should be performed on staphylococcal isolates to ensure that the drug will be effective. Quinupristin and dalfopristin, a synergistic combination of two streptogramins, was approved only for the treatment of infections caused by vancomycin-resistant *Enterococcus faecium*. It also has activity against MRSA but is generally not used in such cases today.

### Aminoglycosides

Aminoglycosides, such as gentamicin, tobramycin, and amikacin, have long been used in combination with other drugs against difficult-to-treat, Gram-positive and Gram-negative infections. Although they act at the site of the bacterial ribosome, aminoglycosides are bactericidal against most aerobic Gram-negative bacteria. Because of the risk of serious renal toxicity and ototoxicity associated with their use and the fact that they do not have good levels of activity at some sites of infection, use of aminoglycosides now is limited at many centers to only serious or multidrug-resistant, Gram-negative infections. In addition, either gentamicin or another aminoglycoside, streptomycin, used in conjunction

with penicillins or vancomycin is needed to achieve cure in the treatment of endocarditis due to susceptible *Enterococcus* spp.

### Miscellaneous Agents

Vancomycin is a glycopeptide that inhibits cell wall and cell membrane synthesis and is bactericidal against *Streptococcus*, *Enterococcus*, and *Staphylococcus* spp. It has been a commonly used antimicrobial in U.S. hospitals for MRSA infections for 20 years but is being used less as newer drugs for enterococci and *S. aureus* are available. Resistance emerged in the late 1980s among enterococci and in the late 1990s among *S. aureus*. The new MICs for vancomycin against *S. aureus* are sensitive  $\leq 2$ , glycopeptide-intermediate *S. aureus* (GISA) 4 to 8, and vancomycin-resistant *S. aureus* (VRSA)  $\geq 16$ .

Daptomycin, a lipopeptide, disrupts the cell membrane and has activity against Gram-positive cocci similar to vancomycin. It has favorable activity in the treatment of skin and soft tissue infections and right-sided endocarditis. However, daptomycin is not reliable for the treatment of primary pneumonia. Studies are in progress for high-dose use.

A new class of compounds, the oxazolidinones, was developed mainly to address the growing concern over emerging vancomycin resistance. Currently, linezolid is the only available oxazolidinone; it inhibits protein synthesis and is considered bacteriostatic against Gram-positive organisms. It is indicated principally in the treatment of infections caused by vancomycin-resistant enterococci and MRSA. It has nearly 100 percent bioavailability; therefore, it may be given orally. Monitoring for thrombocytopenia should occur with long treatment durations ( $> 2$  weeks), and caution should be advised if a patient is taking a monoamine oxidase inhibitor or selective serotonin reuptake inhibitor to avoid precipitating the serotonin syndrome.

Polymyxin is a class of antibiotic that was used in the 1960s and 1970s for Gram-negative infections, especially pneumonia, but was abandoned because of its association with renal toxicity. The two forms available are colistin sulfate and colistimethate sodium. Physicians are using polymyxin again because of the emergence of multidrug-resistant Gram-negative infections, such as *P. aeruginosa* and *Acinetobacter baumannii*, which are resistant to all other available agents, including carbapenems and aminoglycosides.

Trimethoprim-sulfamethoxazole is a synergistic combination of drugs that together exhibit a bactericidal effect by inhibiting bacterial folate synthesis, an important metabolic pathway. Current clinical use includes the treatment of *Pneumocystis jirovecii* pneumonia (PCP), infections due to *Nocardia* spp., and infections involving *Stenotrophomonas maltophilia*, a multidrug-resistant, Gram-negative nosocomial pathogen. In addition, this drug may be used in its oral form to treat the epidemic of unique strains of MRSA that cause community-associated skin and soft tissue infections, but caution should be used because the drug has been associated with acute kidney disease.<sup>4</sup>

Rifampin, a rifampicin, is likely familiar to the infection preventionist because it is used as prophylaxis in significant exposures to patients with meningitis due to *Neisseria meningitidis*. Rifampin also has activity against most MRSA. However, when used alone, resistance often develops quickly due to point mutations in the gene encoding the bacterial RNA polymerase, where rifampicins exert their effect on bacterial growth and survival. Rifampin typically is used as adjunctive therapy for MRSA infection in a patient with an infected prosthetic device or mechanical valve. Rifampin and rifabutin are used in combination with other agents in the treatment of latent or active disease due to *M. tuberculosis*. Rifaximin is used in the treatment of *C. difficile* colitis.

Metronidazole is the only nitroimidazole currently in use in the United States. It is virtually unsurpassed for its activity in treating anaerobic infection. Because the active drug precursor requires conversion into its active form by an enzyme found only in anaerobic bacteria, metronidazole has no activity against aerobic bacteria. It usually is used as part of combination therapy to treat bacterial infection. Exceptions include the treatment of colitis due to *C. difficile*. Additional, unique indications for metronidazole include parasitic infections, such as vaginitis caused by *Trichomonas vaginalis* or intestinal infections due to *Entamoeba histolytica* or *Giardia lamblia*.

No discussion of antibacterials would be complete without mention of topical and orally nonabsorbable antimicrobials used for treating superficial infections as prophylaxis against infection under certain circumstances, and for eradicating colonization. A wide variety of drugs have been used for this purpose, including bacitracin, neomycin, polymyxin B, mupirocin, and fusidic acid. Among these agents, mupirocin is of special interest to infection preventionists. This agent, when applied topically to the anterior nares, is part of a regimen for decolonization with MRSA. That process is described in **93. Staphylococci**.

## ANTIVIRALS

Antivirals are available for many common and life-threatening viruses. Acyclovir was the first widely used antiviral drug, owing to its infrequent toxicity and activity against a common family of human viruses, the *Herpesviridae*. Although acyclovir is available in an oral form, it is poorly absorbed; the derivatives of acyclovir, valacyclovir and famciclovir, overcome this problem and for most indications are the preferred oral agents. All of these agents are active against herpes simplex viruses (type I and II). Most patients infected with herpesviruses are managed as outpatients; however, severe infections in immunocompromised patients often require inpatient treatment. Likewise, encephalitis due to herpes simplex requires inpatient, IV acyclovir therapy.

Although acyclovir and related agents are less active against varicella-zoster virus, they retain meaningful activity against this virus, which is responsible for chickenpox as a manifestation of primary infection and shingles, or herpes zoster, as a manifestation of secondary or recurrent infection. Most cases of chickenpox in immunocompetent individuals do not require inpatient therapy; however, treatment of patients with herpes zoster using acyclovir or one of its derivatives may reduce the commonly seen complication of postherpetic neuralgia.

Acyclovir and related drugs possess some activity against the cause of infectious mononucleosis, Epstein-Barr virus, but this infection does not routinely require antiviral therapy in immunocompetent patients. In contrast, because these agents are active agent precursors that are converted into their active form by a viral thymidine kinase enzyme, acyclovir and its derivatives have little or no activity against cytomegalovirus (CMV), which commonly infects immunocompromised patients but lacks a thymidine kinase. Ganciclovir and valganciclovir are the first-line drugs used to treat most CMV infections. IV ganciclovir is the drug of choice for serious life-threatening pneumonitis in solid organ and bone marrow transplant patients. Ganciclovir and valganciclovir are associated with significant bone marrow toxicity. In patients who cannot tolerate or fail to have a response to ganciclovir, foscarnet may be used as second-line therapy to treat serious CMV infections.

Other antivirals include cidofovir with activity against herpesviruses 6 and 8, Epstein-Barr virus, and a variety of other DNA viruses, including papillomavirus, polyomavirus, poxvirus, and adenovirus. Anti-influenza drugs include amantadine and rimantadine for influenza A and zanamivir and oseltamivir (neuraminidase inhibitors) for influenza A and B. Ribavirin covers a wide range of RNA and DNA viruses and now has as its main use the treatment of Hepatitis C (when used in combination with interferon) in



addition to its long-standing use in treating children with respiratory syncytial virus. Interferons stimulate the patient's own immune system to control and in some cases clear Hepatitis B, Hepatitis C, herpesvirus, and papillomavirus. Although not in common clinical use for this purpose, when given prophylactically, interferons also can protect patients from infection with respiratory viruses, including respiratory syncytial virus (RSV), rhinovirus, and coronavirus.

Antiretrovirals revolutionized the care of patients infected with HIV with the advent of antiretroviral therapy (ART). ART consists of combinations of various drugs that act in combination to suppress viral replication effectively; the therapy has improved survival markedly. Although the focus of ART is long-term therapy among outpatients, these drugs are now commonly used for postexposure prophylaxis of healthcare personnel exposed to HIV. The major categories of antiretrovirals (and several representative agents) include the entry inhibitor, maraviroc; the fusion inhibitor, enfuvirtide; nucleoside or nucleotide reverse transcriptase inhibitors (NRTI; e.g., emtricitabine, lamivudine, tenofovir, zidovudine); nonnucleoside reverse transcriptase inhibitors (NNRTI; efavirenz, nevirapine, etravirine, rilpivirine); protease inhibitors (PIs; e.g., atazanavir, darunavir, ritonavir); and raltegravir, an integrase inhibitor. Combinations of these drugs make up the typical postexposure prophylaxis regimen.

## ANTIFUNGALS

The availability of highly active imidazoles, such as fluconazole and itraconazole, has had a major impact on the treatment of some human fungal infections, such as candidemia. Fungal sensitivities are now available to ensure treatment is appropriate and to alert the infection preventionist when a resistant strain is increasing in the hospital. Attention should be given when instructing patients to take imidazoles because absorption is better during certain times. The newer triazoles, voriconazole and posaconazole, are used for invasive aspergillosis and disseminated candidiasis, and voriconazole has a unique indication for serious fungal infections caused by *Scedosporium apiospermum*. The echinocandins are a class of compounds that inhibit the synthesis of glucan, an essential component of the fungal cell wall. Among the echinocandins, caspofungin is indicated for refractory aspergillosis, candidiasis, and some invasive candidal infections. At this time, anidulafungin and micafungin are primarily used for invasive candidal infections, although they also cover *Aspergillus*.

Amphotericin B deoxycholate, a suspension of a polyene compound that weakens the fungal cell membrane through interaction with ergosterol, has largely been replaced by the antifungals already discussed because they are efficacious without the renal and hepatic side effects. The decrease in side effects is significant, even in comparison with the lipid formulations of amphotericin B (Amphotec, Abelcet, and AmBisome). Should they need to be used, they are still effective against cryptococcosis, histoplasmosis, invasive aspergillosis, and other serious infections caused by yeasts or molds, with the exception of *S. apiospermum*. Flucytosine is a nucleoside analogue that is additive with amphotericin in the treatment of infections due to *Candida* spp. and *Cryptococcus neoformans*.

## ANTIPARASITICS

Although parasitic infections constitute many of the most common infections in the world, they occur relatively infrequently in the United States. Drugs such as chloroquine, primaquine, quinine, mefloquine, and doxycycline are used for the treatment or prophylaxis of malaria, a protozoan infection associated with significant morbidity and mortality in endemic regions. Schistosomiasis, caused by a platyhelminth, is treated with praziquantel. The treatment of nematodes (roundworms) includes ivermectin and albendazole. Some antiparasitics are only available in the United States from the Centers for Disease Control and Prevention (CDC).

# Indications for Antimicrobial Use

## PATHOGEN-DIRECTED THERAPY

Appropriate reasons for antimicrobial use are categorized as pathogen directed, empirical, or prophylactic. Pathogen-directed therapy describes antimicrobial use when the microbial pathogen has been determined based on the results of traditional culture, serology, or other methods, such as polymerase chain reactions (PCR), to detect distinct nucleic acids of the microbial pathogen.<sup>5</sup> If a culture has been used to recover the offending microbe and that microbe is a bacterium or yeast, antimicrobial susceptibility results may be made available. In pathogen-directed therapy, the use of the narrowest spectrum antimicrobial is believed to reduce the emergence of antimicrobial resistance and superinfection. Minimizing the cost of therapy also is important whenever equivalent alternatives are available.

Although therapy based on a positive nucleic acid amplification (e.g., PCR) test or other nonculture diagnostic test is considered pathogen directed, susceptibility results are not available to tailor therapy. To overcome this problem, a culture sometimes is performed in tandem to confirm the nonculture diagnostic test result and provide an organism for future susceptibility testing. Whenever a nucleic acid amplification test is performed on a sputum sample for tuberculosis, a smear and culture also should be performed for confirmation and susceptibility testing. However, the nucleic acid amplification test result may be able to provide a much more rapid answer as to whether the patient likely has tuberculosis, rather than waiting the full 4 to 6 weeks for *Mycobacterium tuberculosis* culture results.

In other instances, the nonculture result directs therapy against a pathogen with a predictable susceptibility pattern. A nucleic acid amplification test result that is positive in the case of a sexually transmitted disease (STD) caused by gonorrhea or *Chlamydia* routinely triggers therapy that has been recommended by consensus public health guidelines, but these sexually transmitted diseases, as well as *C. difficile* colitis, PCP, and other infections are treated immediately on the basis of a consistent clinical picture.

## EMPIRICAL THERAPY

When no definitive information about a causative pathogen is available (although Gram stain can be highly suggestive), therapy is said to be empirical. Typically, hospitalized patients are sufficiently ill to warrant treatment before culture and sensitivity results are available, and therapy while the results of cultures are pending may represent most empirical therapy. Especially in hospitalized patients, appropriate cultures, usually including more than one blood culture, should be collected before the initiation of therapy. The site of infection determined clinically (e.g., lung, urinary tract) and host factors (e.g., HIV, organ transplant patient) give an indication of likely pathogens and should shape the decision regarding empirical therapy. Empirical therapy, compared with pathogen-directed therapy, is broader in spectrum due to uncertainty about the causative agent.

## PROPHYLAXIS

Antimicrobial use that is designed to prevent infection rather than treat known or suspected infection is deemed prophylactic. Surgical antimicrobial prophylaxis is the most common type of prophylaxis and it is indicated for surgical procedures in which the risk of wound infection is high enough to show significant benefit of prophylaxis.<sup>6</sup> This is exemplified best in operations involving placement of a prosthetic device, in which an infection would be a major cause of morbidity or mortality (e.g., prosthetic heart valve placement), and operations in patients with severe immunosuppression.



Basic principles of antimicrobial prophylaxis in surgery should be recognized. The antimicrobial spectrum of the drug chosen should be appropriate for the organisms most likely to cause infection. These are most commonly *Staphylococcus* spp. or *Streptococcus* spp., even in abdominal surgeries, in which other organisms predominate in the bowel flora. Adequate tissue levels of the antimicrobial, usually a first-generation cephalosporin, should be present throughout the operative procedure from the time of first incision onward. The duration of prophylactic antimicrobial use should be as short as necessary to minimize the emergence of resistant organisms, reduce the incidence of side effects, and reduce cost; this translates in most cases to a single preoperative dose and occasionally an additional dose or two if surgery duration is prolonged. In general, any time the skin or mucosa is incised, prophylaxis should be considered, whether the wound is clean, clean-contaminated, contaminated, or dirty. Surgical prophylaxis should also be considered for patients whose physical status, as measured by the American Association of Anesthesiologists (ASA) score, is three or more out of five—meaning severe systemic disease is present. Other unique medical conditions requiring antimicrobial prophylaxis include the prevention of endocarditis in patients with high-risk valvular lesions, spontaneous bacterial peritonitis in patients with ascites, and malaria in patients traveling to endemic areas. Certain types of prophylaxis are given immediately after exposure to a high-risk pathogen that causes disease, such as meningococcal meningitis and HIV.

## Strategies to Predict and Improve Patient Outcome

### FACTORS THAT AFFECT OUTCOME

Five major factors contribute to successful antimicrobial therapy: (1) prompt institution of an appropriate antimicrobial; (2) the "bug" factor, related to the virulence and susceptibility of the infecting organism; (3) the "drug" factor, related to the activity of the antimicrobial at a particular site of infection; (4) the "host" factor, related to the underlying condition and immunocompetence of the patient; and (5) the "site" factor, related to the fact that infections at certain body sites (e.g., meninges, heart valves) are inherently more difficult to treat for a variety of reasons.<sup>7</sup> Although one usually can have an impact only on the first factor, an awareness of each of the remaining four is essential for choosing the most appropriate antimicrobial. Selection of an antimicrobial agent that is highly active according to in vitro susceptibility test results is crucial; however, under some circumstances, this intervention alone is of limited value. In the management of infected prosthetic material, the removal of the prosthesis rather than the result of in vitro susceptibility testing would be most predictive of patient outcome. Likewise, the outcome of a patient with an abscess or intra-abdominal infection in most cases is affected much more by surgery or percutaneous drainage than by antimicrobial therapy.

In addition to choosing the most appropriate antimicrobial, the most appropriate dose and route of administration must be selected to improve outcome. The dose must be high enough to be therapeutic (i.e., sufficient to inhibit or kill the organism at the site of infection) but low enough to minimize toxicity. In certain circumstances, host factors require modification of the dose. The presence of renal failure requires a dose reduction of antimicrobials excreted primarily by the kidney (e.g., aminoglycosides, fluoroquinolones, trimethoprim, tetracycline, vancomycin, and all  $\beta$ -lactams except nafcillin and ceftriaxone). Likewise, hepatic insufficiency requires a dose reduction of antimicrobials excreted primarily by the liver (e.g., chloramphenicol, clindamycin, doxycycline, macrolides, metronidazole, rifampin, sulfamethoxazole, ceftriaxone, nafcillin). The site of infection also may influence administration of the antibiotic. In central nervous system infections, the antimicrobial dose frequently needs to be increased for a successful outcome, whereas in urinary tract infections, lower antimicrobial doses are appropriate.

The initial administration of antimicrobials to hospitalized patients is usually via the IV route so that therapeutic levels can be achieved quickly and reliably. IV administration in most cases also results in higher blood levels than can be achieved via the oral route. The exception is for drugs that are exceptionally well absorbed by the gastrointestinal tract, such as fluconazole, the fluoroquinolones, linezolid, and metronidazole. However, even in the case of drugs that are not as well absorbed, sufficient levels usually can be achieved via oral administration so that infected, hospitalized patients can be switched rapidly from IV to oral antimicrobials after an initial response to therapy. This is termed *switch therapy* and has been studied most widely as a means to reduce length of hospitalization and overall healthcare costs for patients with community-associated pneumonia.<sup>8</sup>

Antimicrobials interact in a variety of ways when coadministered. Some antimicrobials directly inactivate others; for example, piperacillin/tazobactam and aminoglycosides inactivate each other when added to the same IV bottle. Antagonism, which is distinct from inactivation, describes the condition of two coadministered antimicrobials that become less effective than either one administered alone. Tetracycline, a bacteriostatic drug, may interfere with the action of penicillin, a bactericidal and cell wall synthesis inhibitor, by preventing cell growth and division. *Synergy* describes the condition when two coadministered antimicrobials are more effective than what the simple addition of the two agents would predict. In the treatment of endocarditis due to *Enterococcus* spp., in which bactericidal activity is necessary to achieve cure, this can be provided by the synergistic combination of a protein inhibitory agent, such as an aminoglycoside, with a cell wall--active agent, such as penicillin or vancomycin.

## DESCRIPTION OF ANTIBIOGRAM

Although the responsibility of publishing an antibiogram traditionally has been assumed by the clinical laboratory, periodic preparation and dissemination of institutional resistance patterns provide infection prevention personnel insights into what antimicrobial classes are most used and potentially misused. Infection preventionists should be involved in the preparation of the antibiogram and aware that there are guidelines regarding this issue available from the Clinical and Laboratory Standards Institute (CLSI).<sup>9</sup>

An antibiogram simplifies multiple patients' antimicrobial sensitivity information at an institution into a single number for pathogens of interest in an effort to monitor trends emerging in drug resistance. Antibiograms help answer questions in two main areas: clinical care (what antimicrobial would be best to use in this hospital for this pathogen?), and infection prevention strategies (has the resistance of this pathogen to this antimicrobial changed in this hospital to warrant augmenting or diminishing our infection prevention interventions?). With resistance increasing, limited resources, and clinical questions pending, antibiograms are a useful tool in medicine.

The technical details of generating an antibiogram are contained in the CLSI document M39-A2, whereas the following is a brief, pertinent summary for the infection preventionist.<sup>9,10</sup> An antibiogram report should be presented at least annually. Data should be analyzed when at least 30 isolates are tested for a given pathogen, and only the first isolate should be included from patients with multiple positive cultures, regardless of the body fluid tested or the antimicrobial susceptibility pattern. Incidentally, because an antibiogram considers only the first isolate, infection preventionists should know that the microbiology laboratory is the place to inquire about the number of any multidrug-resistant isolate of interest. At least 30 diagnostic, not surveillance, isolates of a species should be included in an analysis to provide a meaningful number, and only then for drugs that are routinely tested. Antibiograms should report the proportion of susceptible isolates, not isolates with intermediate susceptibility. However, penicillin-intermediate susceptibility is of interest for *S. pneumoniae*. For *S. pneumoniae*, the proportion susceptible to cefotaxime or ceftriaxone using both the meningitis and nonmeningitis breakpoints should

also be included. When calculating the proportion of susceptibility for *S. aureus*, include the subset for MRSA.

An antibiogram should include a table with pathogens with the total number of isolates listed against antimicrobials (Figure 26-3). The figure reveals, for example, that there were 48 isolates of *S. pneumoniae* with 81 percent sensitive to tetracycline. The value for penicillin and *S. pneumoniae* has two values, one each for the meningitis and nonmeningitis breakpoints. The 2009 CLSI document M39-A3 emphasizes that an antibiogram may be generated for specific units in an institution; note that Figure 26-3 is only for patients outside of the intensive care unit.<sup>9</sup>It will also highlight that antibiograms could underestimate the activities of drugs for multidrug-resistant strains in specific units. For example, if *Klebsiella* strains are analyzed together, the activities of drugs against non-*Klebsiella pneumoniae* carbapenemase producers will be underestimated.

	Total # Isolates	Ampicillin	Ampicillin/Sulbactam	Oxacillin*	Penicillin	Penicillin/Tazobactam	Cefazolin	Ceftriaxone	Cefepime	Imipenem	Acetaminophen	Gentamicin	Tobramycin	Amikacin	Ciprofloxacin	Levofloxacin	Clindamycin	Tetracycline	Trimethoprim/Sulfamethoxazole	Vancomycin
<i>Enterococcus faecalis</i>	187	100										18**								98
<i>Staphylococcus aureus</i>	298		36		36												82	85	98	100
MRSA Only	298		0		0												75	87	99	100
<i>Staphylococcus coagulase-negative</i>	80		22				22													100
<i>Streptococcus pneumoniae</i> ***	48			water			water									100		81	75	100
<i>Acinetobacter</i> spp.	32	41					28	34	75	7	38	47	88	34	34					41
<i>Enterobacter aerogenes</i> ***	32	48					91	75	100	100	78	97	97	100	94	97				97
<i>Enterobacter cloacae</i>	48	25			77		87	91	100	89	81	83	100	77	79					88
<i>Escherichia coli</i>	207	43	43		34	80	83	95	100	83	89	90	99	98	88	88	71	76		
<i>Klebsiella pneumoniae</i>	86	76			91	85	88	88	100	88	92	88	94	89	89		78	86		
<i>Proteus mirabilis</i> ***	51	88	34		100	88	98	98	100	82	90	92	98	72	82					76
<i>Pseudomonas aeruginosa</i>	34				85		70	88	70	88	82	82	82	89	59					
<i>Senftenbergia</i> ***	31	3			90		97	100	100	90	93	87	100	87	100					100

\* Nafcillin is the formulary equivalent of oxacillin

\*\* Synergy likely when used with ampicillin or vancomycin

\*\*\* Represents 2006 and 2007 data

† Non-CLSI/CLSI breakpoints

NON-ICU PATIENTS

Figure 26-3.

Sample of an antibiogram for patients from non-ICU locations within the University of Louisville Hospital, 2007.

[View Image](#)

## Antimicrobial Resistance

Antimicrobial resistance is an important global public health problem that is particularly acute among hospitalized patients. The detrimental impact of antimicrobial resistance on the treatment outcome of healthcare-associated infections (HAIs) has been increasingly documented not only in terms of increased morbidity, but also as a contribution to increased mortality. In addition, resistance

contributes significantly to increased healthcare costs. The excess U.S. healthcare costs attributed to just six common forms of resistance in nosocomial pathogens has been estimated to exceed \$13.3 million.<sup>11</sup>

## ANTIMICROBIAL SUSCEPTIBILITY TESTING

In vitro (laboratory) susceptibility testing provides important predictive information of whether an infection is likely to respond to a particular antimicrobial in vivo (patient). The most commonly used test method includes the microtiter broth dilution systems using trays of small-volume wells consisting of various concentrations of antibiotic read via an automated, commercial instrument.<sup>12</sup>Other test methods include agar disk diffusion (Kirby-Bauer) and the antimicrobial gradient diffusion method (E-test or D-test), in which a reagent strip consisting of a gradient of antimicrobial is placed on an agar plate to produce a gradient of concentrations in the medium.

Each of the above-mentioned test methods is performed and interpreted using standardized criteria according to published recommendations of the CLSI.<sup>13</sup>Although disk diffusion test results are expressed qualitatively, broth, agar, and E-test results may be expressed quantitatively as an MIC. Although these systems consist of a broth dilution test, manufacturers commonly limit the number of concentrations

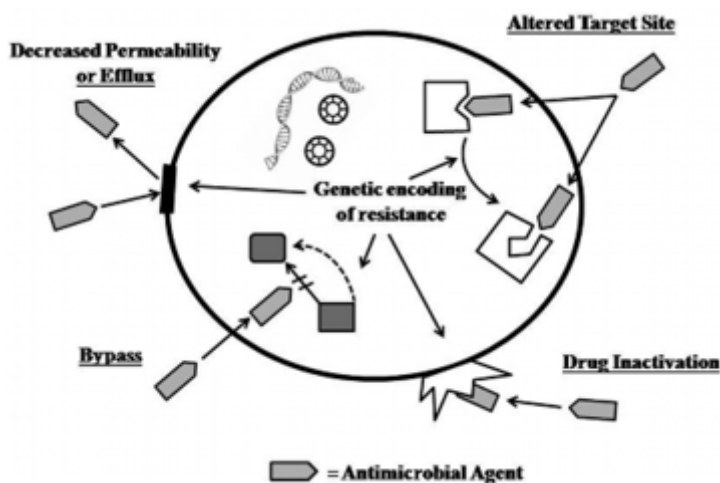
tested to only breakpoint concentrations that separate susceptibility categories. For example, breakpoint concentrations for ciprofloxacin tested against *E. coli* would be 1 µg/mL (a low concentration of the drug at which there is *inhibition of growth, and thus the E. coli* is considered susceptible); and a breakpoint of 4 µg/mL (a high concentration of the drug at which there is *growth, and thus the E. coli* is considered resistant). If growth is present at 1 µg/mL but inhibited at 4 µg/mL, the ciprofloxacin is considered intermediate.

Clinical laboratories typically report results using the recommended qualitative result categories of susceptible, intermediate-susceptible, and resistant based on the breakpoints set by CLSI.

*Susceptible* means that the drug is likely to be effective for the treatment of infection using a standard dosage. *Intermediate-susceptible* means that the drug is likely to be effective only at body sites where it is physiologically concentrated (e.g., the urine for most drugs) or at other body sites if higher-than-usual dosing regimens are used. *Resistant* means that the drug is unlikely to be effective for the treatment of infection unless predictably toxic dosages are used. Laboratories should consider not including MIC or breakpoint concentrations without interpretation provided because they may be misinterpreted.

## MECHANISMS

Major mechanisms of antimicrobial resistance include drug inactivation and alteration in target site, decreased permeability or efflux, and bypass of a metabolic pathway (Figure 26-4). Drug inactivation occurs when a bacterium produces an enzyme that can destroy or inactivate the antimicrobial; bacteria may produce β-lactamase enzymes that destroy penicillins and cephalosporins. Alternatively, drug receptor or target sites may undergo alteration, as observed in MRSA when the penicillin binding protein (PBP) is altered to PBP2a, coded for by the better known *mecA* gene. Changes in drug permeability or an efflux of drug may be observed, as in the case of *P. aeruginosa* that has developed resistance to the carbapenems. Finally, bacteria may develop alternative metabolic pathways to bypass the pathway that was inhibited by the antimicrobial; resistance to trimethoprim-sulfamethoxazole commonly occurs in this manner.



**Figure 26-4.**

Major cellular mechanisms of antimicrobial resistance.

[View Image](#)



Resistance develops in microorganisms as a result of either point mutations in existing genes or the acquisition of new genes. Point mutations are random errors that occur during DNA replication, resulting in the substitution of one base pair for another, which may result in the substitution of one amino acid for another in a protein structure or enzyme. These mutations occur infrequently at the correct locations of the bacterial genome necessary to cause resistance

( $10^7$  to  $10^{12}$  per generation); when point mutations are responsible for resistance, it usually is because they have a slight structural change in a drug-receptor or target site. However, because most forms of antimicrobial resistance require complex structural or enzymatic changes, most forms of resistance result from newly acquired genes.

## TRANSMISSION



Point mutations that result in resistance usually occur in the chromosome of the microorganism and are passed on only to daughter cells via cell division; however, mobile genetic elements also exist that can promote the transmission of genes between strains. These include plasmids and transposons. Plasmids consist of a circular segment of extrachromosomal DNA that can replicate itself. A *transposon* is a segment of DNA that can insert itself in the chromosome and be transmitted between cells via a plasmid or even a virus. Together these mobile genetic elements or "jumping genes" are known as *resistance factors* (R factors). Resistance that is carried on R factors is potentially more serious than resistance caused by point mutations in the chromosome because resistance can be spread to different strains or even different species of microorganisms. R factors commonly contain multiple genes conferring resistance to several antimicrobials, whereas point mutations generally confer resistance to only one class of antimicrobials.

Certain resistance genes acquired by a microorganism via an R factor may become stably inserted into its chromosome and, similar to a chromosomal point mutation, be passed on only to daughter cells via cell division. The transmission of such chromosomal resistance may be distinguished epidemiologically from the transmission of R factors in the hospital. Chromosomal resistance is spread among patients as a single strain or clone, and in this sense the resistance is said to be "clonal," whereas R factor resistance usually involves multiple strains or clones and is said to be "polyclonal." Distinguishing a clonal from polyclonal outbreak of resistance in a single species often requires molecular characterization of isolates from several patients. A description of the molecular techniques to perform such characterization in the laboratory is outside the scope of this chapter. See **93. Staphylococci**.

## EXAMPLES

Antimicrobial resistance has been found in hospitals since the advent of penicillin and the discovery of penicillinase-producing *S. aureus* in the 1940s. MRSA first were detected in the early 1960s, shortly after the introduction of methicillin, and aminoglycoside resistance among Gram-negative bacilli first was noted in the 1970s. During the 1970s and 1980s, MRSA spread so widely that vancomycin had to be used increasingly to treat these infections. This set the stage for the development and spread of vancomycin-resistant enterococci (VRE), first in Europe in the late 1980s and then in the United States by the early 1990s. Klevens reported that nearly one in five adults hospitalized with a MRSA infection die.<sup>14</sup>

The 1990s saw that the spread of fluconazole resistance increased among *Candida* spp. (e.g., *C. krusei*, *C. glabrata*, and occasionally *C. albicans*). During this same time, identification of expanded-spectrum  $\beta$ -lactamases (ESBLs) increased in some hospitals. ESBLs are  $\beta$ -lactamases found in common Gram-negative bacteria, such as *E. coli* and *K. pneumoniae*, which confer resistance to all  $\beta$ -lactam drugs except the carbapenems. The most recent form of antimicrobial resistance that has caused concern includes the  $\beta$ -lactamases associated with carbapenem-resistant Enterobacteriaceae (CRE). The media has publicized CRE as a "superbug." CRE is the group of Gram-negative pathogens that are resistant to most antimicrobials, including carbapenems which have been useful for multidrug-resistant pathogens until now. The resistant enzyme may be encoded within a bacteria's own DNA chromosome affecting a whole species, or acquired on a transposon or plasmid affecting a strain of a species. One of the worst outbreaks was with a plasmid mediated *Klebsiella pneumoniae* carbapenemase at a National Institutes of Health (NIH) medical facility in Maryland where 11 of 18 patients died. From an infection prevention perspective, patients with ESBL or carbapenemase multidrug-resistant organisms need to be in contact isolation.<sup>15</sup>

The late 1990s raised concern for vancomycin resistance in MRSA. In 1996, GISA first was reported from Japan<sup>16</sup> and then the United States<sup>17</sup> where VRSA was described in 2002.<sup>18</sup> VRSA resulted from the new acquisition of resistance genes from VRE. Unfortunately, resistance has been reported with linezolid and daptomycin use. Antimicrobial stewardship is critical to preventing antimicrobial prescribing habits that provide an environment conducive to such a resistant pathogen.

## Antimicrobial Stewardship

Strategies other than simply new drug development must be stressed to curb antimicrobial resistance. Healthcare institutions provide care to patients at increased risk of infection who, because they are exposed to antimicrobial selective pressure, are also at risk of colonization or infection by antimicrobial-resistant pathogens. These patients are in close proximity to one another so that resistance is transmitted easily. Just as there has long been understanding of the role of infection prevention in preventing transmission of antimicrobial resistance, there is an increasing awareness of the need to manage antimicrobial use in hospitals more carefully. Antimicrobial stewardship programs are important components of antimicrobial resistant management in healthcare institutions. The Infectious Diseases Society of America (IDSA) has multiple relevant guidelines for this purpose available at <http://www.idsociety.org>. (See Supplemental Resources, Dellit and colleagues.)

## SURVEILLANCE

The surveillance of antimicrobial resistance is an essential first step in identifying priority areas for managing antimicrobial use from an infection prevention perspective versus a pharmacy or cost-containment perspective. In addition to tracking the proportion of isolates that are resistant (i.e., antibiogram), infection preventionists should consider tracking the number of patients who are found on routine cultures to be newly colonized or infected with problem areas of resistance, such as MRSA, VRE, or *C. difficile*. The spread of these forms of resistance may be expressed as episodes of newly detected colonization or infection per 100 admissions or 1,000 patient days; this information is crucial for infection prevention efforts aimed at controlling resistance and antimicrobial use quality improvement. Along with these forms of surveillance, vigilance should be maintained by laboratory and infection prevention personnel with regard to the possible emergence of sentinel resistance patterns, such as vancomycin resistance in *S. aureus*.

## ANTIMICROBIAL MANAGEMENT TEAM

The next step in monitoring and improving antimicrobial use involves antimicrobial auditing. This is accomplished best through the formation of a multidisciplinary antimicrobial team, the members of which should include, if possible, an infectious diseases physician, clinical pharmacists, and personnel from the clinical laboratory and infection prevention.<sup>19</sup> The mission of such a team usually includes controlling antimicrobial costs and improving patient care and reducing resistance. The infection prevention team member should emphasize the latter goals.

With so many members, it is easier to think of the team as having an administration arm and a clinical arm. The administration arm is responsible for identification of potential problem areas either from resistance patterns or from drug costs and consumption data from the pharmacy. Decisions can be made regarding whether targeted or general audits should be undertaken. In either case, guidelines of acceptable use are needed against which to compare practice; these should be developed at the institutional level based on available national or international consensus guidelines. Consensus

guidelines recommending appropriate empirical therapy of common infections now are increasingly accepted as the standard of care. The IDSA Antimicrobial Stewardship guideline outlines evidence-based strategies related to monitoring antimicrobial use.<sup>19</sup> Other general areas where audits can be undertaken include the appropriateness of dosing, whether surgical antimicrobial prophylaxis is used according to the aforementioned described principles, and whether empirical therapy is routinely narrowed to pathogen-directed therapy when culture results become available.

The clinical arm, usually including clinical pharmacist members and infectious diseases physicians and fellows, is responsible for performing audits prospectively or retrospectively. Prospective or "real-time" audits offer the advantage of uncovering additional information regarding why antimicrobials are used and, more importantly, the opportunity to intervene by making recommendations of how to improve antimicrobial use. They also collect and enter data into a database to monitor their interventions over time. The clinical arm of the antimicrobial program is critical for a program's success because it enforces the policies and antimicrobial guidelines drafted by the administrative arm of the program.

Success of any program depends on improving practice wherever inappropriate antimicrobial use is found. Elements critical for the success of the antimicrobial team will be determined by a local application of the IDSA guidelines, such as having appropriate personnel, dedicated time, appropriate education, and clear goals.<sup>20</sup> Several methods have been used to improve antimicrobial use with an aim of controlling resistance. The first of these methods is intervention, such as computer-assisted drug protocols and feedback of prescribing habits in relation to guidelines. These methods could include the prospective, real-time interventions made by members of an antimicrobial team conducting audits, as discussed earlier. Reports should be a part of feedback, and feedback should be given to prescribers as well as people to whom the prescribers are accountable. For example, a report to the chiefs of medicine and surgery could include lists of the most common infections treated, the most common antimicrobials prescribed in the hospital, and an overall summary of internal medicine and surgeons' compliance, respectively, with the hospital antimicrobial guidelines.<sup>20</sup> The second method is a paternal approach that restricts access to certain drugs, such as exclusion from the formulary, placement on a list of drugs requiring approval before dispensing, and alternating the use of different classes of antimicrobials to prevent the emergence of resistance (i.e., antibiotic cycling). The third method is an academic approach involving didactic instruction and the promulgation of institutional antimicrobial guidelines among prescribers.<sup>21</sup> As an alternative to formal didactic instruction, education of prescribers has been done by means of written information and face-to-face interactions (i.e., counter-detailing) carried out by clinical pharmacists, nurse practitioners, or physicians. Use of a combination of strategies to improve antimicrobial use has been shown to be more efficacious than use of a single method.<sup>22,23</sup>

As part of this collaborative approach, some attention should be paid to the influence of the pharmaceutical industry on prescribing. Whatever method is used, as a general rule, interventions to improve antimicrobial use should be implemented in collaboration with the pharmacy and therapeutics and quality improvement committees and members of the hospital administration.

## International Perspective

There are several aspects to understanding antimicrobial use and resistance and how to improve antimicrobial use that require modification to apply to settings outside the United States and North America. Drugs other than those described earlier may be used commonly in the international setting.



Certain drugs that have been granted FDA approval are not available overseas and vice versa. In addition, drugs may be used outside the healthcare setting (i.e., in the community or in animal food production) differently and in such a manner that they are more likely to affect resistance in hospitals. For example, the use of avoparcin, a glycopeptide related to vancomycin, has long been used in animal food production in Europe and East Asia but not the United States and has been linked to VRE found among hospitalized patients in regions where it is used.<sup>24</sup> Likewise, the availability of antimicrobials over-the-counter without a prescription in many developing countries may influence resistance patterns, albeit predominantly in community pathogens.

Another major area to consider is how cultural differences and differences in healthcare financing may influence the effectiveness of measures designed to improve antimicrobial use. In some cultures, the clinical services are hierarchical, and recommendations made by a clinical pharmacist member of the antimicrobial team are much less likely to be followed. Instead, physician-to-physician interaction or interaction among senior physicians and administrators may be necessary to effect a change in prescribing patterns.

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## **Section 4**

### **Basic Principles of Infection Prevention Practice**

## Hand Hygiene

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### Abstract

*Hand hygiene is a critical component of patient and employee safety. Effective patient safety and infection prevention and control programs require that healthcare personnel be familiar with hand hygiene recommendations and consistently adhere to them. This chapter provides the reader with information to successfully implement a hand hygiene program in compliance with the Centers for Disease Control and Prevention guidelines,<sup>1</sup> the World Health Organization's Clean Care Is Safer Care campaign,<sup>2</sup> and The Joint Commission requirements.<sup>3</sup>*

### Key Concepts

- Hands contaminated with transient bacteria pose a significant risk for transmission of infection.
- Hands with dermatitis or other skin breakdown are more susceptible to becoming colonized with transient bacteria, including multidrug-resistant organisms.
- Healthcare personnel need to be educated about when and how to perform hand hygiene.
- Healthcare personnel adherence to hand hygiene recommendations must be monitored and feedback given.
- Multimodal interventions to improve hand hygiene should be implemented based on results of monitoring and institutional assessment of high-risk areas.
- Improved hand hygiene practices have been associated with reduced healthcare-associated infection rates.
- Alcohol-based hand sanitizers do not kill bacterial spores and soap and water also show limited efficacy against *Clostridium difficile* spores.<sup>4</sup> Use of gloves for care of all patients known or suspected

to harbor spore-forming organisms (e.g., *Bacillus anthracis*, *C. difficile*) is crucial, followed by hand washing if available or hand hygiene with alcohol if sinks are not easily accessible.

- Alcohol-based hand sanitizers have limited efficacy against norovirus and, therefore, in outbreak situations hand washing with soap and water is preferred.<sup>5</sup>
- Patients should be offered the opportunity to clean their hands during the day and should be encouraged to participate in their care by either reminding staff to clean their hands or by providing positive reinforcement for hand hygiene compliance.
- The Joint Commission's National Patient Safety Goal 7.01.01 requires facilities that choose to be accredited by The Joint Commission to comply with the Centers for Disease Control and Prevention's 2002 hand hygiene guideline or the World Health Organization's Clean Care Is Safer Care campaign.

## Background

Hand hygiene has been accepted as the single most important measure to prevent transmission of infection and is the cornerstone of most infection prevention and control programs. Observational studies of hand-washing compliance reviewed in the 2002 Centers for Disease Control and Prevention (CDC) hand hygiene guidelines reported rates averaging less than 40 percent.<sup>1</sup> Reasons for poor

adherence include lack of knowledge, increased demands with less time, irritated and dry hands, lack of soap and paper towels, inaccessible sinks, shortage of sinks, belief that wearing gloves obviated need for hand washing, forgetfulness, skepticism about the value of hand washing, lack of role models, lack of administrative priority for hand hygiene, and lack of administrative sanctions.

The major shift in focus in the 2002 CDC hand hygiene guideline was the introduction and promotion of alcohol-based hand sanitizers as a primary way for healthcare personnel (HCP) to decontaminate their hands. Since that time the World Health Organization (WHO) has launched the Clean Care is Safer Care campaign and there has been a focus on monitoring and behavior modification to improve hand hygiene adherence.

## Basic Principles

### GENERAL KNOWLEDGE

Waterless, alcohol-based hand rubs are now the preferred products for routine hand hygiene in healthcare settings unless hands are visibly soiled. The WHO and CDC guidelines recommend that HCP be provided with a readily available alcohol-based hand rub product.<sup>1,2</sup> Data suggest that this

recommendation will increase the frequency of HCP hand hygiene and result in decreased incidence of dermatitis caused by the drying effects of soap and water and abrasive towels. Artificial fingernails or nail extenders are prohibited for those having direct contact with patients at high risk (e.g., in intensive care units or operating rooms), but there was not enough evidence for the guideline to make a recommendation regarding jewelry and rings for HCP outside the operating room.

The CDC and WHO guidelines clearly delineate administrative responsibility for making improved hand hygiene adherence an institutional priority and for providing appropriate administrative support and financial resources. The Joint Commission's National Patient Safety Goal 7.01.01 requires facilities to comply with the WHO's recommendations or CDC's hand hygiene guideline, which lends additional support for this important initiative to prevent transmission of infection and improve patient safety.

Recommendations for increased use of waterless hand hygiene products do not negate the need for hand-washing sinks. The American Institute of Architects' *2010 Guidelines for Design and Construction of Health Care Facilities* addressed this issue by continuing to require hand-washing stations, defined as "an area providing a sink with hot and cold water supply and a faucet that facilitates easy on/off mixing capabilities. This station includes provision of cleansing agents and drying capability."<sup>6</sup>In addition, these guidelines require that there be one hand-washing station in the patient's bathroom for patient use and another hand-washing station in the patient room, ideally near the door, for HCP use.

## DEFINITION OF TERMS<sup>1</sup>

Alcohol-based hand rub is a solution that contains 60 to 95 percent alcohol and is designed to be applied to hands to reduce the number of viable microorganisms on the hands. Although ethyl alcohol and isopropyl alcohol are both effective against bacteria, fungi, and viruses, isopropyl alcohol has slightly greater activity against bacteria and ethyl alcohol has greater activity against viruses.

Antimicrobial soap is a soap that contains an antiseptic agent. Antiseptic agents are antimicrobial substances that are applied to the skin to reduce the number of microbial flora. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan. In the United States, the Food and Drug Administration (FDA) regulates antiseptic agents.

Antiseptic hand wash is washing hands with water and soap containing an antiseptic agent. Antiseptic hand rub is applying an antiseptic hand rub product to all surfaces of the hands to reduce the number of microorganisms present without rinsing with water. Hand antisepsis refers to either antiseptic hand wash or antiseptic hand rub. Hand hygiene is a general term that applies to hand washing, antiseptic hand rub, or surgical hand antisepsis.

Hand washing is washing hands with plain (i.e., nonantimicrobial) soap and water. Surgical hand antisepsis is an antiseptic hand wash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident hand flora. Antiseptic hand wash preparations often have persistent antimicrobial activity.

Visibly soiled hands are hands that show visible dirt or that are visibly contaminated with proteinaceous material, blood, or other body fluids (e.g., fecal material or urine).

## ROUTINE HAND WASHING AND HAND ANTISEPSIS

### *PRODUCT SELECTION*

To improve hand hygiene adherence, facilities are required to provide an alcohol-based (60 to 95 percent alcohol) hand rub for routine hand antisepsis "in areas in which high workloads and high intensity of patient care are anticipated."<sup>1</sup>The WHO supports use of alcohol-based hand sanitizers for widespread use, especially in developing countries where access to clean water may be limited.<sup>2</sup>The WHO has consulted with Muslim religious leaders to gain assurance that use of alcohol for hand hygiene is culturally acceptable.

In addition, the CDC guidelines require plain lotion soap or an antimicrobial soap to be available for routine hand washing and hand antisepsis. Although the selection process may start with products covered under the facility's purchasing agreements, the CDC guideline makes clear that cost should not



be the primary factor influencing product selection. To maximize acceptance, both the WHO and CDC guidelines recommend that employees be involved in product trials and selection.

Alcohol-based hand sanitizers vary considerably in their consistency, odor, and added emollients. Consideration should be given to the type of sanitizer most appropriate to the care setting (foam, gel, liquid, or wipe), whether an appropriate amount of product is consistently dispensed, and whether there are problems with dispensers such as dripping. Product for dispensers should be packaged in unit-dose inserts to prevent "topping-off" partially empty dispensers. Antimicrobial-impregnated wipes (towelettes) were not considered as effective as gels, foams, or liquids at the time of the 2002 CDC guidelines. However, since that time, the type and amount of alcohol in these wipes has changed. Recent studies have shown hand wipes containing ethanol to be effective against both bacteria<sup>7</sup> and viruses.<sup>8</sup> Wipes may also be convenient to promote patient hand hygiene.

Infection preventionists need to review the CDC guideline carefully to determine whether their specific facilities need only plain lotion soap or only antimicrobial soap as an alternative to the waterless product or whether both plain lotion soaps and antimicrobial soaps should be installed at sinks. The advantage of installing only an antimicrobial (e.g., 2 percent chlorhexidine gluconate [CHG]) at sinks is that personnel will not have to make a choice between plain soap or an antimicrobial, ensuring that an antimicrobial is used when indicated. Regardless, it is important to select products with a low potential for skin irritation. Part I of the CDC guideline contains an excellent discussion on the specific antimicrobial formulations, which should be reviewed before product selection.

Because hand skin dryness is a frequently cited reason for noncompliance with hand hygiene, the CDC guidelines recommend hand lotions or creams be provided to HCP "to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing."<sup>1</sup> Infection preventionists must check the manufacturer's recommendations to ensure that components of the lotion do not inactivate antimicrobial soaps. Manufacturers often sell soaps and lotions that are compatible to make purchasing decisions and pricing easier. Consideration should be given to locating hand lotion dispensers in centralized locations such as at charting areas and in lounges.

### *DISPENSER LOCATION*

The CDC guideline recommends that dispensers for the alcohol-based product be conveniently located at the entrance to each patient room, examination room, treatment room, and similar areas. Alternatively, the dispensers can be located inside the rooms near the door or adjacent to each bed. Some dispensers can be fitted with counters that track the date and time of each use.<sup>9</sup> These can help facilities to locate dispensers in the most effective locations and to remove those that are not routinely used. Individual pocket-sized containers carried by HCP also have been suggested, but concerns have been expressed about the inability of keeping contaminated hands from contacting clothing and for product loss and the associated expense.

Although alcohol-based hand rubs are extremely safe, they are potentially flammable.<sup>10</sup> Therefore, the maximum amount that can be placed in a single fire compartment is 10 gallons in dispensers, and 5 gallons stored in cabinets or areas approved for flammable materials. Care must be taken to ensure fire safety.<sup>11</sup>

The current National Fire Protection Association Life Safety Code permits the use of alcohol-based hand rub solutions in patient rooms, corridors, and suites of healthcare facilities. Adoption of this tentative

interim amendment allows the installation of dispensers in corridors, provided that the following conditions are met:<sup>11</sup>

- The corridor width is 6 ft or greater, and dispensers are separated by at least 4 ft.
- The maximum individual dispenser fluid capacity is 1.2 L for dispensers in rooms, corridors, and areas open to corridors and 2.0 L for dispensers in suites of rooms.
- The dispensers are not installed over or directly adjacent to electrical outlets and switches.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces are permitted only in smoke compartments with fire sprinklers.
- In addition, each smoke compartment may contain a maximum aggregate of 10 gallons of alcohol-based hand rub solution in dispensers and a maximum of 5 gallons in storage.

Because local or state fire code requirements may differ from national codes, facilities should check with their local authorities regarding any restrictions. Fire safety regulations related to these products are expected to change as more data become available.

### *INDICATIONS FOR HAND HYGIENE*

The CDC 2002 hand hygiene guideline recommends several specific situations for hand hygiene including separating occasions for use of soap and water versus alcohol-based hand sanitizers.

Briefly, hand washing with soap and water is recommended if hands are visibly soiled, before eating and after using the bathroom, and if the HCP is exposed to spore-forming organisms such as *B. anthracis* or *C. difficile*. The 2011 CDC guidelines for control of norovirus outbreaks<sup>5</sup> and the updated Society for Healthcare Epidemiologists of America compendium of strategies to prevent *C. difficile* infection<sup>12</sup> also recommend using soap and water hand washing during outbreaks of infection.

Alcohol-based hand sanitizer is recommended before and after patient care, before donning sterile gloves, before inserting invasive devices, after contact with a patient's intact skin, after removing gloves, after contact with objects and equipment in the patient's immediate vicinity, and when moving from a contaminated to a clean site on the same patient.

The WHO recognized that the multiple indications for hand hygiene were difficult to remember, and sought to simplify the message with the "My 5 Moments for Hand Hygiene," which has become widely adopted. The five moments include:

- Before patient care
- Before an aseptic procedure
- After any contact with blood or other body fluids—even if gloves are worn
- After patient care
- After contact with the patient's environment

### *HAND HYGIENE TECHNIQUE*

When using an alcohol-based hand rub, it is important to check the manufacturer's recommendation for volume of product and ensure that the appropriate amount is dispensed. If not enough product is dispensed or if the product is not applied to all parts of the hands, antimicrobial efficacy may be limited. After dispensing the product, personnel should rub all areas of hand surfaces together until they are

dry. HCP with larger hands may need to dispense two dollops of product when performing hand hygiene. A good rule is that it should take 15 to 20 seconds of rubbing for the hand sanitizer to dry.

When using soap and water, hands should be wet with water that is not too hot, then product should be applied per manufacturer's recommendations, and hands should be rubbed together vigorously, covering all skin surfaces and under rings, for at least 15 seconds. Hands should be rinsed thoroughly, so that no product is left, and then dried with a disposable towel. A dry towel is then used to turn off the water faucet.

## SURGICAL HAND ANTISEPSIS

### *PRODUCT SELECTION*

Either an antimicrobial soap or an alcohol-based surgical hand rub *with persistent activity* may be used. Alcohol-based formulations are the most effective at immediately lowering bacterial counts. The next most effective agents, in order of decreasing activity, are CHG, iodophors, triclosan, and plain soap. Persistent antimicrobial activity is another important characteristic for a surgical scrub, and the most effective are CHG (2 or 4 percent), triclosan, and iodophors. Alcohol has no residual antimicrobial effect. Combination formulations of 60 to 90 percent alcohol and 0.5 to 1 percent CHG equal or exceed the persistence of CHG alone<sup>1</sup> and are approved for surgical hand antisepsis. PCMX needs further studies to establish its efficacy as a surgical scrub. Hexachlorophene is absorbed into the blood after repeated use and, therefore, is seldom used as a surgical scrub.

Users should be involved in the selection of surgical hand antiseptic products, and cost should not be the primary factor influencing product selection. Efficacy and low-irritancy potential should be prime selection criteria. Product replacements for dispensers should be packaged in unit-dose inserts to prevent "topping off" partially empty dispensers.

### *TECHNIQUE*

Whether using an *antimicrobial soap* and water or alcohol-based surgical hand rub product for surgical hand antisepsis, hand and arm jewelry should be removed before the surgical scrub, and hands should be washed including removal of debris from underneath fingernails using a nail cleaner under running water prior to the first scrub of the day. Hands and arms should be thoroughly dried after the hand wash before beginning alcohol-based surgical hand preparation. Either type of product should be used according to manufacturer's instructions, and hands and arms should be thoroughly dry before donning sterile gloves. Artificial fingernails or nail extenders are not to be worn by personnel in operating rooms.

## STAFF EDUCATION AND EFFECTIVE INTERVENTIONS

Education of HCP about the role of hand hygiene in preventing infections is basic and is required by The Joint Commission in facilities that they accredit.<sup>3</sup> The CDC has an interactive Web-based education program (<http://www.cdc.gov/handhygiene/training/interactiveEducation>) along with other hand hygiene promotional materials (<http://www.cdc.gov/handhygiene/training/interactiveEducation/index2.htm>). WHO's Clean Care Is Safer Care also has hand hygiene materials available for download (<http://www.cdc.gov/handhygiene/training/interactiveEducation/index2.htm>).

Unfortunately, education alone seldom leads to adequate adherence to hand hygiene in healthcare. Multimodal, multidisciplinary strategies are more likely to lead to change and improve hand hygiene

practices.<sup>13,14</sup> Factors related to hand hygiene improvement include administrative support, convenient and acceptable products and dispensers, monitoring and feedback, role modeling of excellent hand hygiene practices, and motivational or incentive programs. In addition, the behavioral and motivational components of hand hygiene adherence are receiving more attention as it becomes clearer that these have a profound impact on practice.<sup>15,16</sup> A recent Cochrane review identified weaknesses in the design of most hand hygiene studies,<sup>17</sup> supporting the need for better research in this area. A top priority should be assessing which "bundles" of interventions are most likely to support sustained improvement in hand hygiene practice.

## MONITORING FOR ADHERENCE

The CDC and WHO guidelines and The Joint Commission require monitoring of HCP adherence to recommended hand hygiene practices, and that feedback is given about their performance. There are several possible performance indicators, and each method of measurement has advantages and drawbacks. There are automated systems that have the potential to monitor all patient care episodes and provide "just in time" reminders to staff who have forgotten to clean hands before or after patient care.<sup>18</sup> These systems cannot distinguish all of the different hand hygiene opportunities, so are largely confined to monitoring entrance and exit from the patient's bedside. These systems are still largely in development, are expensive, require system maintenance, and only a few have been shown to promote sustained improvement in hand hygiene adherence.<sup>19,20,21</sup> The following are acceptable methods for measuring hand hygiene adherence:<sup>22</sup>

- Directly observe a sample of hand hygiene opportunities and calculate the rate of adherence (number of hand hygiene episodes performed/number of hand hygiene opportunities) by ward or service.
  - Some organizations observe the WHO five moments for hand hygiene,
  - Some have simplified the measurement to focus on hand hygiene before and after care episodes (wash in, wash out).<sup>23</sup> This proves easier to monitor, but it is unclear whether this narrower focus impacts patient outcome.<sup>24</sup>
  - In addition to monitoring the rate of adherence, facilities may also assess the quality of hand hygiene adherence (time spent per hand hygiene episode, whether soap was used during hand washing, etc.).
- Monitor the volume of specific hand hygiene products (e.g., soap, hand rub, hand lotion) used per 1,000 patient days.
- Employ a system of video monitoring,<sup>25</sup> or use of sensing devices that have been validated to monitor hand hygiene episodes per patient care episode.

## Conclusions

Hand hygiene remains a foundation of patient safety and infection prevention, yet achieving and sustaining adequate adherence remains a challenge. Single interventions such as in-service education, distribution of information leaflets, workshops and lectures, and performance feedback on compliance rates have been associated with transient, but not sustained, improvement in hand hygiene compliance.

The complex dynamic of behavioral change requires a combination of education, motivation, and system change. Some organizations are focusing on system and culture change as a way to improve hand hygiene compliance. There are few scientifically rigorous studies that elucidate the best combination of interventions to improve hand hygiene adherence.<sup>17</sup>

Over the last several years, governments, regulatory agencies, payers, and the public have become more aware of, and invested in, preventing HAIs. Increased emphasis on hand hygiene in healthcare from outside agents may prove an important factor in promoting adherence.

## Future Trends

Although there is a large body of literature on hand hygiene, there are still unresolved issues that require further investigation. Recent endemic infections and outbreaks with spore-forming organisms such as *C. difficile* and viruses that are inherently harder to kill with alcohol (norovirus) call for research on whether changing hand hygiene protocols for patients with these organisms is warranted, and if so, under what circumstances. Many studies of hand hygiene lack the scientific rigor needed to elucidate the most important elements of bundled interventions. Some areas for future research include the following:

- Improved methods for rigorously studying hand hygiene compliance over a sufficient period of time to establish correlation of specific "bundles" of interventions with improved hand hygiene outcomes.<sup>17</sup>
- Studies to better establish correlation of hand hygiene practices with infection outcomes.<sup>26</sup>
- Studies to better assess the human factors associated with hand hygiene practices.
- Establishing benchmarks and best method(s) for monitoring hand hygiene adherence.<sup>22,27</sup>
- Assessing whether hand hygiene before donning clean gloves is important for infection prevention.
- Whether use of alcohol-based hand rubs for routine care of *C. difficile*<sup>28</sup> or norovirus patients is adequate (i.e., not changing the standard practices recommended by guidelines), or whether soap and water hand washing is superior in clinical settings and warrants deviation from usual practices.

## Supplemental Resources

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## Standard Precautions

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### Abstract

*Standard Precautions are guidelines that outline the minimum set of interventions that are required for preventing the transmission of microorganisms. They provide a foundation for infection prevention measures that are to be used for all patients in every healthcare setting. There are many factors that contribute to the consistent use of Standard Precautions within healthcare facilities. Administrative support is necessary to ensure infection prevention is an integral component of the organizational structure. Healthcare personnel must be educated and empowered to be accountable for providing safe care to all patients by incorporating Standard Precautions into the interventions and education they provide. There are several key components that the Healthcare Infection Control Practices Advisory Committee identifies that constitute the Standard Precautions guidelines.<sup>1</sup> Hand hygiene, respiratory hygiene and cough etiquette, appropriate use of personal protective equipment, safe work and injection practices, and environmental cleaning, as well as patient placement, are all elements essential in breaking the cycle of microorganism transmission. In today's global society, it is imperative that all facilities and settings that provide healthcare meticulously practice Standard Precautions to prevent transmission of known, as well as unknown threats of emerging pathogens protecting all persons including healthcare personnel, patients, and the community at large.*

### Key Concepts

- Transmission of infection requires a source of infection, a mode of transmission, and a vulnerable host.
- Application of Standard Precautions is the first step in breaking the cycle and preventing the transmission of microorganisms between healthcare personnel, patients, and the environment.
- Standard Precautions are intended to be utilized for the care of all patients, in all settings in which healthcare services are rendered, even in the absence of a suspected or confirmed infectious

process.

- Standard Precautions are utilized to protect both healthcare personnel and patient(s) from infection preventing the spread of microorganisms between hosts (person-to-person, person to environment to person).

## Background

Standard Precautions are the foundation for prevention of transmission of infectious agents in all healthcare settings.<sup>1,2,3</sup> The concept was introduced in 1991 in the Bloodborne Pathogen Standard issued by the Occupational Safety and Health Administration (OSHA).<sup>2</sup> Initial recommendations for the prevention of transmission of infectious agents were included in the original Universal Precautions and Body Substance Isolation guidelines. These guidelines address the potential for transmission of infection through unprotected contact with the patient's blood, body fluids, secretions, or excretions or from contact with their mucous membranes or nonintact skin. In 1996, the Healthcare Infection Control Practices Advisory Committee (HICPAC) incorporated Universal Precautions and Body Substance Isolation guidelines into a new guideline called Standard Precautions.<sup>1</sup> The most recent additions published in 2007 included respiratory hygiene guidelines and the use of a surgical mask during certain high-risk invasive procedures including placement of central line intravenous catheters and conducting spinal taps.<sup>1</sup> Standard Precaution guidelines include infection prevention practices that are intended to break the cycle through which microorganisms are transmitted between healthcare personnel, patients, and the environment. In order for Standard Precautions to be effective, there are several essential components of infection prevention that must be present in all healthcare settings.<sup>1,4</sup>

- Administrative support: The role of administration is to provide an operational framework in which Standard Precautions are seamlessly incorporated into all aspects of patient care. Organizations must provide guidance and support as well as monitor adherence to Standard Precautions so that correction of system errors may occur when identified. Adequate financial resources and support from human resources ensure that supplies and staffing remain adequate so as to guarantee that adherence to Standard Precautions can be maintained. Organizations must be prepared to meet the needs of emerging threats at all times.
- Education: Education regarding Standard Precautions is mandated by OSHA and is supported by the Centers for Disease Control and Prevention (CDC).<sup>1,2</sup> All employees operating within a healthcare environment require initial education on infection control practices, including Standard Precautions, prior to the start of employment as well as annual training to maintain competency.
- Policies and procedures: Policies and procedures must meet all regulatory requirements and be current. Policies and procedures must be available to all employees to ensure that access to reference materials is readily available.
- Institutional culture: Prevention of microorganism transmission is dependent on healthcare personnel (HCP) adherence to Standard Precautions. Individual employees must be accountable for following all facility policies and procedures; however, they must also be fully supported by the administration. In a culture in which patient and HCP safety is an expectation, adoption of safe work practices are integral and valued in preventing the transmission of infectious agents in healthcare.<sup>3</sup>

## Basic Principles

The foundation for Standard Precautions was published most recently in the HICPAC/CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*.<sup>1</sup> This

document is a comprehensive guideline that provides recommendations for the prevention of transmission of microorganisms in all healthcare settings.

OSHA mandates in the Bloodborne Pathogen Standard that HCP must be protected from exposure to blood or other potentially infectious materials.<sup>2</sup> OSHA accepts the CDC's Standard Precautions guidelines as sufficient to protect HCP from potential exposures.

## Recommendations for Standard Precautions

Standard Precautions are the first line of defense in preventing the transmission of microorganisms between HCP, patients, families and visitors, and the environment. They may be applied successfully in any environment including hospitals, ambulatory care settings, rehabilitation settings, long-term care settings, and the home. The components of Standard Precautions are aimed at breaking the cycle of infection by interrupting the method in which transmission occurs. Some interventions require that HCP utilize special supplies, policies, or procedures, but their effectiveness depends on the adherence of the HCP to these essential guidelines.

### HAND HYGIENE

Hand hygiene is an essential component in the adherence to Standard Precautions.<sup>1,2,3</sup> It is the single most effective measure that can be undertaken to decrease the transmission of organisms between HCP, patients, and the environment. Hand hygiene requires the use of either plain or antimicrobial soap or waterless alcohol-based hand hygiene products. There are multiple opportunities for the proper use of hand hygiene to break the cycle of transmission. As a part of Standard Precautions, hand hygiene must be performed:

- After touching blood, body fluids, secretions, and excretions
- After touching contaminated items
- Immediately after removing gloves
- Between patient contacts

Further guidelines regarding hand hygiene can be found in **27. Hand Hygiene**.

### RESPIRATORY HYGIENE/COUGH ETIQUETTE

Respiratory hygiene and cough etiquette interventions are intended to limit the spread of infectious organisms from persons with potentially undiagnosed respiratory infections.<sup>1,3</sup> In order for respiratory hygiene interventions to be effective, early implementation of infection control measures needs to occur at the first point of entry within a healthcare setting and maintained throughout the duration of the visit.<sup>1</sup>

The effort of respiratory hygiene interventions are targeted at patients and accompanying significant others with respiratory symptoms and applies to any person entering a healthcare setting with signs of respiratory illness including cough, congestion, rhinorrhea, or increased production of respiratory secretions.

The five main elements of an effective respiratory hygiene program include:

- Education of HCP, patients, and visitors on the signs and symptoms of respiratory illness
- Posted signs at facility entries with instructions for prevention of transmission of respiratory illness in languages of the local population
- Easy availability of source control measures (tissues, surgical masks) to enable patient and visitors to cover sneezes and coughs and mask persons with a cough
- Easy and frequent availability of hand hygiene located close to other source control supplies including the facility entrance and waiting rooms
- Encourage patients or visitors with respiratory symptoms to sit apart from other people in the waiting room, more than 3 feet apart, or place in a separate area when feasible<sup>1</sup>

HCP with respiratory illness should avoid providing direct patient contact. A barrier mask should be worn by HCP who demonstrate signs and symptoms of respiratory illness but need to provide direct patient contact. Barrier masks are also indicated in some instances where the HCP may be infectious prior to the onset of symptoms such as with exposure to varicella or measles.

## PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) is designed to protect the wearer's skin, eyes, mucous membranes, airways, and clothing from coming into contact with infectious agents.<sup>1,2,3,4</sup> The selection of PPE is made based on the tasks being performed and anticipated level of exposure the employee expects to encounter. Components of PPE can be used alone or in combination to provide the desired level of protection. Mucous membranes and skin with compromised integrity are portals of entry that are highly susceptible to infectious agents; therefore, it is important that appropriate protective measures be taken.

- Fluid-resistant gowns: worn when HCP anticipate performing patient care activities or procedures in which exposed skin or clothing are likely to be exposed to any patient blood, body fluids, secretions, or excretions.
- Gloves: worn when HCP anticipate touching the mucous membranes or nonintact skin of a patient or any patient blood, body fluids, secretions, or excretions. Gloves should also be worn when handling or touching equipment or environmental surfaces that have been contaminated. Hand hygiene should always be practiced immediately when gloves are removed.
- Barrier masks or barrier masks with shields: worn when HCP anticipate sprays of blood or body fluids, particularly respiratory secretions. HCP, patients, or visitors in healthcare settings also wear barrier masks to limit the spread of potentially infectious respiratory secretions. In some cases, HCP should consider wearing barrier masks when providing direct patient care if at risk of spreading respiratory illness after unprotected exposure prior to becoming symptomatic such as in the case of influenza.
- Surgical masks: worn by HCP to protect the patient from infectious agents in the HCP's nose or mouth during sterile procedures such as insertion of catheters or injections into spinal or epidural spaces during lumbar puncture procedures.
- Goggles/face shields: worn by HCP to protect the eyes and face of the wearer from sprays of respiratory secretions, blood, or body fluids. They should be worn when the HCP anticipate participating in a procedure that has the potential to generate splashes or sprays of blood, body fluids, secretions, or excretions. Personal eyeglasses or contact lenses do not provide adequate protection and are not considered acceptable eye protection. The use of face shields allows HCP to

wear their own personal eyeglasses and increase protection to other areas of the face, including the eyes.

## SAFE WORK PRACTICES

In an effort to limit exposure to potentially infectious microorganisms, HCP must take care to keep gloved and ungloved hands from touching their own mucous membranes.<sup>1</sup> Patients should be positioned to direct any splatters or sprays of patient blood, body fluids, secretions, or excretions away from the face of the HCP. Prior to providing patient care, HCP need to ensure that their PPE is positioned properly and secured to avoid potential contamination during repositioning of PPE.

Resuscitation/ventilation masks should be available and easily attainable in all areas where resuscitation may occur, including those where they are needed infrequently. HCP should always use a barrier for resuscitation such as a mouthpiece, resuscitation bag, or other ventilation device to prevent direct contact with secretions from the patient.

## ENVIRONMENTAL CLEANING

Cleaning and disinfecting of all surfaces, equipment, and devices in patient care areas are an integral part of Standard Precautions.<sup>1,2,3</sup> Cleaning of all medical equipment and devices, including computers and technological devices, that enter patient care areas is important to prevent transmission of infectious organisms. Noncritical patient care equipment should be cleaned and disinfected after each patient use. All soiled medical equipment and devices should be handled in a manner that prevents the transfer of microorganisms to others and the environment. Contaminated equipment that must be cleaned and disinfected must be stored in an area that is separate from clean supplies and equipment. HCP should wear gloves when handling equipment that is contaminated or visibly soiled and perform hand hygiene immediately after removal of gloves. Soiled linen should be handled utilizing a method that prevents microorganisms from being transmitted to other people and the environment. Further guidelines regarding handling linen can be found in **111. Healthcare Textile Services** and **107. Environmental Services**.

## SAFE INJECTION PRACTICES

Safe injection practices are essential to ensuring both patient and HCP safety.<sup>1,3,5</sup> HCP should always use a sterile, single-use disposable syringe and needle for each injection given. Care needs to be taken to ensure that all injection equipment and medication vials remain free from contamination. Sterile packaging should only be opened immediately prior to use and the vial access diaphragm should be disinfected with an approved antiseptic immediately prior to accessing.<sup>1,5</sup> It is highly recommended that single dose vials be used over multiple dose vials, especially when the medications will be administered to multiple patients. This decreases the risk of the solution becoming contaminated from multiple accesses to the vial. Used needles should never be recapped, bent, or broken and any safety device present should be engaged immediately after use.<sup>1,2,5</sup> If recapping is necessary, only a one-handed technique should be used. All used sharps should be placed immediately in an approved puncture-resistant container that is designated for sharps disposal.

## PATIENT PLACEMENT

In the event that a patient is determined to be at increased risk for transmission of microorganisms, the patient should be placed in a single-patient room when available.<sup>1</sup> Those patients that are likely to contaminate the environment, do not maintain appropriate hygiene, or are at increased risk for acquiring



infections or developing adverse outcomes following infection should be considered for single room placement. When single patient room is not available, patient spacing should be maintained at a minimum of 3 feet or more. Privacy curtains may be pulled and used as an environmental barrier.

## Global Considerations

Standard Precautions are appropriate for use worldwide to prevent transmission of infections. The ease of international travel has brought with it effortless transportation of highly contagious diseases from one continent to another. In the aftermath of severe acute respiratory syndrome (SARS) caused by a novel coronavirus in 2003 and the H1N1 influenza pandemic in 2009, after retrospective analysis, it was determined that if Standard Precautions had been utilized correctly, the spread of these diseases could have been decreased significantly.<sup>1,4,6</sup> After the SARS pandemic, Standard Precautions were expanded to include respiratory hygiene and cough etiquette to help limit the spread of potentially infectious respiratory secretions between patients, visitors, and HCP. In addition to concerns for potential epidemics or pandemics, the number of patients infected or colonized with extremely drug-resistant microorganisms is rapidly increasing.<sup>7</sup> Standard Precautions are an essential component in the prevention of the transmission of these organisms. Patients can be admitted to any healthcare setting with unidentified infections or colonization with these organisms. Maintaining strict adherence to Standard Precautions needs to occur to prevent transmission from these patients to HCP, the environment, and ultimately other patients. Healthcare facilities must always be prepared for the looming threat of the next pandemic or global threat.<sup>8</sup> Healthcare facilities should maintain or ensure access to an adequate level of supplies. They should also ensure that policies and procedures are in place to guide containment and prevention of transmission of highly infectious agents.

## Conclusions

Standard Precautions are the primary defense in preventing the transmission of microorganisms between HCP, patients, and the environment. The components of Standard Precautions are aimed at breaking the cycle of infection by interrupting the method in which transmission occurs. While it is the role of the healthcare administration to ensure infection prevention is an important component of the organizational structure, the value of the interventions remains the responsibility of HCP and their accountability for adhering to these essential guidelines. When Standard Precautions are correctly implemented, the spread of infectious diseases can be prevented, leading to improved health of both HCP and patients.<sup>4</sup>

## Supplemental Resources

Boyce JM, Pittet D; Healthcare Infection Control Practices Advisory Committee; HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recomm Rep* 2002;51(RR-16):1-45.

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## Isolation Precautions (Transmission-based Precautions)

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### Abstract

*Infection prevention barrier precautions provide a foundation for infection prevention practices that span the spectrum of healthcare settings. Modern healthcare delivery has expanded from the traditional hospital to other settings that include home care, ambulatory care, freestanding specialty care sites, and long-term care. Having a standardized approach to barrier precautions, also referred to as isolation precautions, both simplifies and unifies the actions that healthcare personnel take, regardless of the setting. The 2007 Guideline for Isolation Precautions has several features that older guidelines lack, including the addition of several newer diseases and emerging pathogens, as well as describing techniques to prevent transmission in home care and ambulatory care. The goals of this chapter are to provide an overview of the isolation guidelines published in 2007 by the Healthcare Infection Control Practices Advisory Committee and the Centers for Disease Control and Prevention to address the emergence of new pathogens and concern for evolving pathogens, and to examine practical and effective ways to control the spread of multidrug-resistant organisms. The reader can access the document 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings at <http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>. Additional guidelines and references pertaining to isolation and prevention of infectious agents are listed in the Supplemental Resources section of this chapter.*

## Key Concepts

- The risk of transmission of infectious agents occurs in all healthcare settings, including acute care facilities, long-term care settings, ambulatory care facilities, and home health care. Infections can be transmitted from patient-to-patient via healthcare personnel, the shared environment, or medical equipment and devices.
- Isolation Precautions are only a part of a comprehensive infection prevention program. An isolation system includes Standard Precautions that are applied to all patients and Transmission-based Precautions.
- Unidentified patients who are colonized or infected with infectious agents represent a risk to other patients and healthcare personnel.

## Background

The following fundamental elements are needed to prevent transmission of infectious agents in healthcare settings by effectively implementing an isolation precautions system.

- Administrative measures: Healthcare organizations must have administrative support for infection prevention efforts. Providing adequate funding for the infection prevention program and adequate staffing through human resources are key elements.
- Infection prevention staffing: The scope and complexity of work that the infection preventionist (IP) performs on a daily basis has expanded, with the increasing complexity of healthcare systems often increasing required qualifications for the IP and the need for additional infection prevention staffing.
- Internal communication with the clinical microbiology laboratory, employee health, the emergency room, and environmental services is fundamental.
- External communication with other healthcare facilities regarding isolation status is pivotal to maintaining infection prevention and can be achieved with patient transfer forms.
- Policies and procedures guiding chemoprophylaxis, postexposure prophylaxis, immunization, and tuberculin screening of healthcare personnel (HCP) are essential.
- A comprehensive educational program on the isolation precautions system must include medical staff or faculty, staff, patients, and visitors.
- Infrastructure support, including access to computer technology and other electronic resources, facilitates outbreak tracking, public health reporting, and data management.

## Basic Principles

The HICPAC/CDC published *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* in June of 2007.<sup>1</sup> A multidrug-resistant organism (MDRO) guideline was released earlier, in the fall of 2006.<sup>2</sup> The 2006 document is a comprehensive guideline for reducing transmission of MDROs in multiple healthcare settings and serves to supplement the 2007 Isolation Precautions guideline.

The Centers for Disease Control and Prevention (CDC)/Healthcare Infection Control Practices Advisory Committee (HICPAC) system for categorizing recommendations is as follows:

- Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
- Category IC. Required for implementation, as mandated by federal and/or state regulations or standards.
- Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
- No recommendation, unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exist. This category assists investigators in determining topics that are in need of further study.

Regulatory agencies, such as The Joint Commission (TJC), and quality groups, such as Leapfrog and the Institute for Healthcare Improvement (IHI), encourage the implementation of all Category IA, IB, and IC recommendations by healthcare facilities.

## Recommendations For Infection Prevention Precautions

### STANDARD PRECAUTIONS

Standard Precautions are applied to all patients in all healthcare settings. The basic concept of Standard Precautions is to treat all patients' blood or body fluids as if they are infectious material. This concept originated from the Bloodborne Pathogen Standard directed by the Occupational Safety and Health Administration (OSHA) in 1991. Terms such as "universal precautions" or "body substance isolation" were coined in response to preventing transmission of bloodborne pathogens. Standard Precautions are a group of infection prevention practices that include hand hygiene and use of gloves, gowns, masks, eye protection, or face shields depending on anticipated exposure. New additions to Standard Precautions included in the 2007 guideline are as follows:

1. Safe injection practices. Because of multiple outbreaks<sup>3,4</sup> of infections attributed to unsafe injection practices, it is recommended to use a sterile single-use needle and syringe for each injection. Use single-use medication vials whenever possible and avoid using multiple dose vials. Avoid reinsertion of used needles in multiple dose vials or solutions, and avoid use of single-use needles and syringes to administer intravenous medication to multiple patients.
2. Special lumbar puncture procedures. Use a facemask during spinal procedures (e.g., lumbar punctures, myelogram, and spinal anesthesia). The use of masks prevents oral contamination during lumbar puncture procedures.<sup>5</sup>
3. Respiratory hygiene/cough etiquette. Respiratory hygiene and cough etiquette<sup>6</sup> include covering the mouth and nose during coughing and sneezing with a tissue or offering a surgical mask to the coughing patient, discarding the mask or tissue appropriately and performing hand hygiene, posting signs in public areas in languages appropriate to the population served, and educating HCP, patients, and visitors.

Further information on Standard Precautions can be found in **28. Standard Precautions**.

### TRANSMISSION-BASED PRECAUTIONS

In addition to Standard Precautions used for all patients, Transmission-based Precautions are used for select patients with specific diseases or pathogens. A category of Transmission-based Precautions including Contact Precautions, Droplet Precautions, Airborne Precautions, and Protective Environment may be used alone or in combination. They are recommended to contain highly transmissible and/or epidemiologically important agents and are based on the mode of transmission of the specific pathogen.

**1. Contact Precautions.** Contact Precautions are used for diseases transmitted by contact with the patient or the patient's environment. Diseases caused by organisms that have been demonstrated to cause heavy environmental contamination, such as vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, or respiratory syncytial virus (RSV) in infants, children, and immunocompromised adults, require gowns and gloves on room entry.

- Patient placement: A single room is preferred; however, patients with the same disease or organism may share a room. In cases where there is a shortage of patient rooms, prioritize patient cohorts by conditions that may foster transmission (i.e., uncontained drainage, stool incontinence), giving them priority for single patient room placement.
- Personal protective equipment (PPE): Wear a gown and gloves on room entry. Change the gown and gloves between patients even if both patients share a room and/or one or both are on Contact Precautions. Always use hand hygiene between glove changes.
- Patient transport: Limit patient transport outside the room to medically necessary purposes. Inform the receiving department of the Transmission-based Precaution status of the patient. Cover or contain potentially infectious body fluids before transport. The transporter should discard contaminated PPE before transport. Don clean PPE to handle the patient at the destination.
- Ambulatory settings, rehabilitation settings, and long-term care settings: Place patients on Contact Precautions in examination rooms as soon as possible. In long-term care and rehabilitation settings, patient placement should be handled on a case-by-case basis. Each facility should make decisions on the basis of infection risks to other patients in the facility.
- Environmental measures: Clean daily with a focus on high touch areas, patient bathrooms, and areas close to the patient. Environmental service workers should don gown and gloves before room entry to clean and disinfect the patient's room. Meticulous environmental cleaning and use of products with a *C. difficile* inactivation label claim combined with adherence to hand hygiene and good laundry practices are recommended to decrease transmission of *C. difficile*.<sup>7</sup> Some viruses and spore-forming organisms are resistant to traditional disinfectants, and use of a 1:10 dilution of bleach solution is recommended.<sup>8</sup> For patients with organisms that are resistant to traditional cleaning methods (e.g., *C. difficile*, norovirus), bleach may be used as an adjunct to cleaning or as a final wipe down of the frequently touched surfaces. It is important to realize that control of resistant pathogens is achieved by implementing a combination of procedures, not just an individual disinfecting product. The use of *no-touch* systems, such as hydrogen peroxide vapor/mist and ultraviolet radiation, in conjunction with traditional cleaning and disinfection methods reduces microorganism on environmental surfaces. These methods are to be used in terminal cleaning only.<sup>7</sup> Copper alloy surfaces and the incorporation of silver into various materials exhibit an antimicrobial effect on microorganisms.<sup>8</sup> Processes for room disinfection should be audited, especially in outbreak scenarios, to ensure compliance.
- Discontinuation of Contact Precautions: Generally, Contact Precautions are discontinued when signs and symptoms of the infection have resolved or according to pathogen-specific



recommendations. For MDROs such as VRE, resistant *Acinetobacter baumannii* (MDR Ab), and carbapenem-resistant Gram-negative organisms (CRO) recommendations are inconclusive. The current guideline is that any colonized or infected patient with CRO and MDR Ab remain on Contact Precautions for the entire length of stay in healthcare facilities.<sup>3,4,9</sup>

- 2. Droplet Precautions.** Droplet Precautions prevent transmission of diseases caused by large respiratory droplets that are generated by coughing, sneezing, or talking. Diseases transmitted by the droplet route include, but are not limited to, influenza, pertussis, and bacterial meningitis due to *Neisseria meningitidis*.
- Patient placement: Facilities should support the empiric use of Droplet Precautions that utilize clinical respiratory syndromes to facilitate timely isolation. Single rooms are preferred; however, patients with the same disease may share a room. Priority should be given to patients with excessive sputum production when single-patient rooms are in short supply. Patients must be spatially separated by at least 6 feet.<sup>10</sup> Draw privacy curtains between patients. Avoid placing immunocompromised patients with patients who are on Droplet Precautions especially if those patients may have adverse outcomes from infection.
  - Personal protective equipment: Wear a surgical mask on room entry. Handle items contaminated with respiratory secretions (e.g., tissues, handkerchiefs) with gloves. Change PPE between patients and perform hand hygiene.
  - Patient transport: Limit patient transport outside the room to medically necessary purposes. If the patient must leave the room, instruct the patient to wear a surgical mask and follow respiratory hygiene and cough etiquette. Once the patient is masked, the patient transporter does not need to wear a surgical mask. Notify the receiving department of the isolation precautions status.
  - Ambulatory settings: Patients who present with clinical respiratory syndromes should be instructed in the practice of respiratory hygiene and cough etiquette and given surgical masks to wear until an examination room can be provided. Place patients requiring Droplet Precautions in an examination room as soon as possible. HCP should don surgical masks on room entry.
  - Long-term care: Make decisions on patient placement on a case-by-case basis after considering all options. Ambulatory patients on Droplet Precautions should be instructed to wear a surgical mask in common areas. All patients should be instructed in the proper use of respiratory hygiene and cough etiquette.
  - Environmental measures: Daily cleaning with hospital-approved disinfectant of high-touch and horizontal surfaces. Environmental services personnel should don a surgical mask before room entry.
  - Discontinuation of Droplet Precautions: Discontinue Droplet Precautions after signs and symptoms have resolved or according to pathogen-specific guidelines.
- 3. Airborne Precautions.** Airborne Precautions are used to prevent transmission of infectious organisms that remain suspended in the air and travel great distances due to their small size (less than 5 µm). Consequently, the concern for transmission of these pathogens in healthcare settings is not typically from face-to-face contact, but rather from airflow patterns within the facility. These diseases include measles, smallpox, chickenpox, pulmonary tuberculosis, avian influenza, and possibly severe acute respiratory syndrome (SARS)-associated coronavirus.<sup>9</sup>
- Patient placement: In acute care and long-term care settings, place patients in an airborne infection isolation room (AIIR) with negative air pressure relative to the corridor. There should be at least 6 to 12 air exchanges per hour, and air should be directly exhausted to the outside.

Monitor the air pressure daily with visual indicators (e.g., smoke tubes, flutter strips) and electronic methods (e.g., maintenance air exchange reports) when possible. Keep the door shut.

- Personal protective equipment: Wear a fit-tested National Institute for Occupational Safety and Health (NIOSH)-approved N95 or higher level respirator for respiratory protection when the patient has suspected or confirmed pulmonary tuberculosis or is undergoing procedures where infectious tuberculosis skin lesions would be aerosolized (e.g., wound irrigation, whirlpool treatment). Similarly, infectious particles may be aerosolized during procedures such as endotracheal intubation; appropriate protective equipment should be worn during these encounters as well. Respiratory protection is also recommended for all HCP whether vaccinated or unvaccinated against smallpox because of the possibility of genetically altered smallpox virus. There are no recommendations for HCP who are immune to measles and chickenpox (varicella) to wear respiratory PPE.<sup>11</sup> Likewise, there is no recommendation for susceptible HCP to wear a surgical mask versus an N95 respirator when caring for patients with measles or chickenpox (varicella).<sup>11</sup> Droplet or even possibly airborne transmission of norovirus in healthcare facilities has recently been documented in the literature. HCP should consider the use of respiratory protection when in close proximity to a vomiting or stooling patient, as infectious virions can be aerosolized and subsequently swallowed. It is believed that droplet and/or airborne transmission may contribute to the early initiation of norovirus outbreaks in healthcare facilities.<sup>12</sup>
- Patient transport: Limit transport of patients to essential medical purposes. If transport out of All is necessary, place a surgical mask on the patient and instruct him/her to observe respiratory hygiene and cough etiquette. Do not place an N95 mask on the patient, as this may further hinder their ability to breathe given their compromised respiratory status. Cover exposed skin lesions with clean bandages and/or clean linens. Transport personnel do not need to wear respiratory protection during transport if the patient is masked and all skin lesions are covered.
- Ambulatory settings: Develop protocols to identify patients with known or suspected airborne infections. Place the patient requiring Airborne Precautions in All as soon as possible. If All is not available, place the patient in an examination room with a portable high-efficiency particulate air (HEPA) filter. If no portable HEPA filter is available, ensure that the patient wears a surgical mask. Regardless of the type of room the patient is in, staff should always don appropriate respiratory protection. Ambulatory care settings, such as the emergency department, are often the first to evaluate a patient presenting with a potentially airborne transmissible infection. Communication between infection prevention and ambulatory care services is essential to ensure that contagious patients are quickly identified and isolated to avoid numerous subsequent employee exposures during the rest of that patient's encounter.
- Environmental measures: Routine cleaning of high touch surfaces is standard. Environmental services personnel should wear an N95 respirator on room entry. After the patient has left the examination room or the patient room, the room should remain unoccupied for enough time to allow for complete air exchange to occur. In some facilities, this time could be 1 hour or less, depending on the air handling capacity of the facility. This practice is applicable in the acute and ambulatory settings.
- Personnel restrictions: Restrict susceptible HCP from entering rooms of patients known or suspected to have measles (rubeola), chickenpox or disseminated zoster (varicella zoster virus), and smallpox if other immune HCP are available. Immunocompromised and pregnant HCP should also be restricted from these patients.
- Discontinuation of Airborne Precautions: Discontinue Airborne Precautions according to pathogen-specific recommendations in the guideline. State and local health departments may

offer further guidance on discontinuing isolation precautions measures for patients with known or suspected pulmonary tuberculosis.

4. **Protective Environment.** A protected environment is recommended for allogeneic hematopoietic stem cell transplant (HSCT) recipients to reduce the risk of invasive environmental fungal infections and other opportunistic pathogens. Facilities may choose to implement some of the measures below for certain immunocompromised patients other than those undergoing HSCT. This evaluation is primarily based on a daily absolute neutrophil count (ANC).

- Environmental controls: Filter incoming air with HEPA filtration that is at positive pressure with relation to the corridor at 12 air exchanges per hour. Air pressure should be monitored daily with visual indicators (e.g., smoke tubes, flutter strips).
- Environmental measures: Clean rooms with techniques that minimize dust. Lower dust levels by avoiding cloth upholstered furnishings; wet dust horizontal surfaces. Avoid carpeting in hallways and patient rooms. Prohibit dried and fresh flowers or potted plants. Patients should receive baths instead of showers due to the aerosolization of potential fungal and bacterial pathogens.<sup>13,14,15,16</sup>
- Nutrition: No recommendation is made for the implementation of restricted diets in HSCT patients. There is no evidence supporting lower infection rates among patients who receive a low bacterial diet versus a normal diet. On the contrary, this restriction has been shown to decrease oral intake, nutrition, and quality of life.<sup>17</sup>
- Patient transport: Limit the time the patient spends outside the Protective Environment. During periods of construction, place an N95 respirator on the patient who can medically tolerate the respirator and is leaving the Protected Environment. If the patient cannot tolerate an N95 respirator, place a barrier mask on the patient when he or she is leaving the Protected Environment. No recommendation is made for fit-testing patients for the N95 respirator.
- Transmission-based Precautions in the Protected Environment: Implement Droplet and Contact Precautions as recommended. Note that immunocompromised patients may experience prolonged shedding of organisms and may need precautions for longer than anticipated. Implement Airborne Precautions in the Protected Environment if an anteroom is present. Positive air pressure is maintained in the patient room with relation to the anteroom. Air in the anteroom is filtered with a portable HEPA filtration unit. If an anteroom is not available, place the patient in All not on the Protected Environment and use a portable HEPA unit to filter the air inside the patient room for fungal spores.

## PREVENTION OF TRANSMISSION OF METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS*, VANCOMYCIN-RESISTANT ENTEROCOCCI, AND OTHER MULTIDRUG-RESISTANT ORGANISMS

MDROs are microorganisms that are resistant to one or more classes of antimicrobial agents. Although the name of the organism may suggest resistance to only one antibiotic (e.g., MRSA or VRE), they are often resistant to multiple classes of antimicrobial agents and can remain on environmental surfaces for months.<sup>5</sup>

MDROs typically include MRSA, VRE, *C. difficile*, and certain Gram-negative bacteria, including those producing extended spectrum beta-lactamases (ESBLs), and carbapenem-resistant Gram-negative organisms. Notable resistant Gram-negative organisms include *Escherichia coli*, *Klebsiella pneumoniae*,

*Enterobacter cloacae*,<sup>1</sup>*Pseudomonas aeruginosa*, and *Acinetobacter baumannii*, which may be resistant to all antimicrobial agents or susceptible to just a single agent. Many Gram-negative organisms are intrinsically resistant, such as *Stenotrophomonas maltophilia*, *Burkholderia cepacia*, and *Ralstonia pickettii*. Some MDROs are regional or associated with certain settings (e.g., long-term care facilities), such as penicillin-resistant *Streptococcus pneumoniae*. When interviewing patients regarding their carbapenem-resistant Enterobacteriaceae (CRE) status, questions should include last hospitalization, last receipt of antimicrobials, and overseas medical care, especially in India or Pakistan (this is especially important in the identification of New Delhi metallo- $\beta$ -lactamase).<sup>1</sup>

Control methods for MDROs are complex and based on seven fundamental elements that include the following:

1. *Administrative measures/adherence monitoring*: Administrative support is essential in preventing and controlling MDROs. The administration needs to be involved in the decision of whether or not to implement active surveillance culturing (ASC) on the basis of the infection prevention risk assessment and the associated increases in laboratory and infection prevention staffing. Administration may also be needed in decisions regarding the following:
  - Activating computer alerts to identify previously infected or colonized patients
  - Providing appropriate number of hand-washing sinks and alcohol gel dispensers
  - Maintaining nursing staffing levels, having dedicated staff for patients with MDROs<sup>3</sup>
  - Enforcing strict adherence to hand hygiene and Contact Precautions practices, including cohorting patients with similar MDROs<sup>3,4,9</sup>
  - Funding for adequate supplies for hand hygiene and Transmission-based Precautions
2. *MDRO education*: Facilitywide, unit-specific education should help to facilitate understanding of MDROs in the facility. Education needs to include rates, trends, and prevention strategies in a format that the learner can easily comprehend. Furthermore, education should create a culture that supports and promotes desired behaviors, such as hand hygiene and Transmission-based Precautions and reduction in device usage. Active communication between facilities when a patient transfers prevents increased transmission between patients within facilities.<sup>3</sup>
3. *Judicious use of antimicrobials*: Evidence-based principles for judicious use of antimicrobials and tools for implementation are key to controlling MDROs. The CDC 2002 campaign to prevent antimicrobial resistance offers tools for implementation at <http://www.cdc.gov/drugresistance/healthcare>. Healthcare facilities may also consider the following:
  - Formulary restriction
  - Education
  - Automatic stop orders
  - Antimicrobial cycling
  - Prior approval programs
4. *Surveillance*: Surveillance of MDROs is critical to any prevention program. Infection preventionists monitor microbiology isolates to detect prevalence and emergence of MDROs. Infection preventionists may also:
  - Calculate MDRO incidence on the basis of clinical culture results
  - Calculate MDRO infection rates
  - Use molecular typing for investigating outbreaks

- Detect asymptomatic carriers using ASC. The decision to use ASC on either all admissions or targeted populations of patients should include careful forethought and preparation. The CDC recommends using such strategies in the event that initial control measures (e.g., implementing Contact Precautions, hand hygiene, and education) do not lead to reductions in MDRO incidence rates. Increasing legislative pressure may direct these programs to focus on a single organism; however, various MDROs persist in healthcare environments or are emerging. The infection prevention and control program should include the following when planning for ASC: providing additional personnel to obtain cultures and additional laboratory personnel to process these cultures, ensuring turnaround time for screening results, monitoring adherence to Contact Precautions, providing a mechanism for communicating results to HCP, and measuring outcomes to evaluate the effectiveness of active surveillance cultures and Contact Precautions.<sup>1,11,18</sup>

11,18

5. *Isolation Precautions*: The 2007 Isolation Guidelines<sup>1</sup> describe the recommendations for the use of Standard Precautions and Contact Precautions in great detail. Discontinuation of Contact Precautions remains an unresolved issue. In facilities that elect to use ASC and not to decolonize, the guideline suggests that patients remain on Contact Precautions throughout their stay in the facility. The guideline further suggests that Contact Precautions may reasonably be discontinued after antimicrobial therapy has ended, the infection has resolved, the patient has not been hospitalized for a least 3 months, and at least three or more surveillance cultures are negative over a 6- to 12-month period.<sup>2,3</sup>
6. *Environmental measures*: Environmental reservoirs have been the source of some outbreaks. Studies have shown a high inoculum of the healthcare-associated pathogen in a cold room with high relative humidity will have the best chance for long persistence of relevant healthcare-associated bacteria, viruses, and fungi.<sup>5</sup> Scrupulous cleaning techniques combined with monitoring adherence to environmental cleaning practices can determine success in controlling MDROs.
7. *Decolonization*: Treating persons colonized with an MDRO, particularly MRSA, is an attempt to eradicate the carrier state in an individual. Decolonization regimens involving MRSA have sometimes been successful; however, decolonization regimens are not generally effective enough to recommend routine use and are not standardized. More recent studies suggest that patients in intensive care units, who are on Contact Precautions and have indwelling devices such as central lines, may be decolonized using daily baths with chlorhexidine gluconate.<sup>19</sup>

## TWO-TIERED APPROACH

The HICPAC MDRO guideline recommends a two-tiered approach for preventing transmission of MDROs. The first tier is composed of general recommendations for all settings. For some facilities, a single case of MDROs comprises an outbreak; for other facilities, MDROs occur at an endemic rate and the introduction of a new strain or an increase in overall MDRO rate would be a cause for concern and impetus to move to the second tier (Tables 29-1 and 29-2).

**Table 29-1** General Recommendations for Routine Prevention and Control of MDROs in Healthcare Settings

Administrative Measures/ Adherence Monitoring	MDRO Education	Judicious Antimicrobial Use	Surveillance	Infection Control Precautions to Prevent Transmission	Environmental Measures	Decolonization

<p>Make MDRO prevention an organizational priority. Provide administrative support and both fiscal and human resources to prevent and control MDRO transmission. <i>(IB)</i> Identify experts who can provide consultation and expertise for analyzing epidemiologic data, recognizing MDRO problems, and devising effective control strategies, as needed. <i>(II)</i></p> <p>Implement systems to communicate information about reportable MDROs to administrative personnel and state/local health departments. <i>(II)</i></p> <p>Implement systems to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving healthcare facilities or personnel prior to transfer of such patients within or between facilities. <i>(IB)</i></p> <p>Support participation in local, regional, and/or national coalitions to combat emerging or growing MDRO problems. <i>(IB)</i></p> <p>Provide updated feedback at least annually to healthcare</p>	<p>Provide education and training on risks and prevention of MDRO transmission during orientation and periodic educational updates for healthcare personnel; include information on organizational experience with MDROs and prevention strategies. <i>(IB)</i></p> <p>Implement systems (e.g., CPCE, susceptibility report comment, pharmacy or unit director notification) to prompt clinicians to use the appropriate agent and regimen for the given clinical situation. <i>(IB)</i></p> <p>Provide clinicians with antimicrobial susceptibility reports and analysis of current trends, updated at least annually, to guide antimicrobial prescribing practices. <i>(IB)</i></p> <p>In settings with limited electronic communication system infrastructures to implement physician prompts, etc., at a minimum implement a process to review antibiotic use. Prepare and distribute</p>	<p>In hospitals and long-term care facilities (LTCFs), ensure that a multidisciplinary process is in place to review local susceptibility patterns (antibiograms), and antimicrobial agents included in the formulary, to foster appropriate antimicrobial use. <i>(IB)</i></p> <p>Implement systems (e.g., CPCE, susceptibility report comment, pharmacy or unit director notification) to prompt clinicians to use the appropriate agent and regimen for the given clinical situation. <i>(IB)</i></p> <p>Provide clinicians with antimicrobial susceptibility reports and analysis of current trends, updated at least annually, to guide antimicrobial prescribing practices. <i>(IB)</i></p> <p>In settings with limited electronic communication system infrastructures to implement physician prompts, etc., at a minimum implement a process to review antibiotic use. Prepare and distribute</p>	<p>Use standardized laboratory methods and follow published guidelines for determining antimicrobial susceptibilities of targeted and emerging MDROs.</p> <p>Establish systems to ensure that clinical micro labs (inhouse and outsourced) promptly notify infection control or a medical director/designee when a novel resistance pattern for that facility is detected. <i>(IB)</i></p> <p>In hospitals and LTCFs:</p> <ul style="list-style-type: none"> <li>Develop and implement laboratory protocols for storing isolates or selected MDROs for molecular typing when needed to confirm transmission or delineate epidemiology of MDRO in facility. <i>(IB)</i></li> <li>Establish laboratory-based systems to detect and communicate evidence of MDROs in clinical isolates. <i>(IB)</i></li> <li>Prepare facility-specific antimicrobial susceptibility reports as recommended by CLSI; monitor reports for evidence of changing resistance that may</li> </ul>	<p>Follow Standard Precautions in all healthcare settings. <i>(IB)</i></p> <p>Use of Contact Precautions (CP):</p> <ul style="list-style-type: none"> <li>In acute care settings: implement CP for all patients known to be colonized/infected with target MDROs. <i>(IB)</i></li> <li>In LTCFs: Consider the individual patient's clinical situation and facility resources in deciding whether to implement CP. <i>(II)</i></li> <li>In ambulatory and home care settings, follow Standard Precautions. <i>(II)</i></li> <li>In hemodialysis units: follow dialysis-specific guidelines. <i>(IC)</i></li> </ul> <p>No recommendations can be made regarding when to discontinue CP. <i>(Unresolved issue)</i></p> <p>Masks are not recommended for routine use to prevent transmission of MDROs from patients to HCP. Use masks according to Standard Precautions when performing splash-generating procedures, caring for patients with open tracheostomies with potential for projectile secretions, and when there is evidence for transmission from heavily colonized sources (e.g., burn wounds).</p> <p>Patient placement in hospitals and LTCFs:</p> <p>When single-patient rooms are available,</p>	<p>Follow recommended cleaning, disinfection, and sterilization guidelines for maintaining patient care areas and equipment.</p> <p>Dedicate noncritical medical items to use on individual patients known to be infected or colonized with an MDRO. Prioritize room cleaning of patients on Contact Precautions. Focus on cleaning and disinfecting frequently touched surfaces (e.g., bed rails, bedside commodes, bathroom fixtures in patient room, doorknobs) and equipment in immediate vicinity of patient.</p>	<p>Not recommended routinely.</p>
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providers and administrators on facility and patient care unit MDRO infections. Include information on changes in prevalence and incidence, problem assessment, and performance improvement plans.(IB)	reports to providers. (II)	<p>indicate emergence or transmission of MDROs. (IA/IC)</p> <ul style="list-style-type: none"> <li>Develop and monitor special care unit-specific antimicrobial susceptibility reports (e.g., ventilator dependent units, ICUs, oncology units). (IB)</li> <li>Monitor trends in incidence of target MDROs in the facility over time to determine if MDRO rates are decreasing or if additional interventions are needed. (IA)</li> </ul>	<p>assign priority for these rooms to patients with known or suspected MDRO colonization or infection. Give highest priority to those patients who have conditions that may facilitate transmission (e.g., uncontained secretions or excretions). When single-patient rooms are not available, cohort patients with the same MDRO in the same room or patient-care area. (IB)</p> <p>When cohorting patients with the same MDRO is not possible, place MDRO patients in rooms with patients who are at low risk for acquisition of MDROs and associated adverse outcomes from infection and are likely to have short lengths of stay. (II)</p>
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**Table 29-2.**Recommendations for Intensified MDRO Control Efforts

Institute one or more of the interventions described herein when (1) incidence or prevalence of MDROs are not decreasing despite the use of routine control measures; or (2) the *first* case or outbreak of an epidemiologically important MDRO (e.g., VRE, MRSA, VISA, VRSA, MDR-GNB) is identified within the healthcare facility or unit (IB). Continue to monitor the incidence of target MDRO infection and colonization; if rates do not decrease, implement additional interventions as needed to reduce MDRO transmission.

**Table 29-2**

Administrative Measures/ Adherence Monitoring	MDRO Education	Judicious Antimicrobial Use	Surveillance	Infection Control Precautions to Prevent Transmission	Environmental Measures	Decolonization
Obtain expert consultation from persons with experience in infection control and the epidemiology of MDROs, either inhouse or	Intensify the frequency of educational programs for HCP, especially for those who work	Review the role of antimicrobial use in perpetuating the MDRO problem targeted for intensified intervention.	Calculate and analyze incidence rates of target MDROs (single isolates/patient; location, service specific). (IB)	Use of Contact Precautions: Implement CP routinely for all patients colonized or infected with a target MDRO. (IA)	Implement patient dedicated use of noncritical equipment. (IB)  Intensify and reinforce training of environmental	Consult with experts on a case-by-case basis regarding the appropriate use of decolonization therapy for patients or staff

through outside consultation, for assessment of the local MDRO problem and guidance in the design, implementation, and evaluation of appropriate control measures. <i>(IB)</i>	in areas where MDRO rates are not decreasing. Provide individual or unit-specific feedback when available. <i>(IB)</i>	Control and improve antimicrobial use as indicated. Antimicrobial agents that may be targeted include vancomycin, third-generation cephalosporins, antianaerobic agents for VRE, third-generation cephalosporins for ESBLs, and quinolones and carbapenems. <i>(IB)</i>	Increase frequency of compiling, monitoring antimicrobial susceptibility summary reports. <i>(II)</i>	Don gowns and gloves <i>before or upon entry</i> to the patient's room or cubicle. <i>(IB)</i>	staff that work in areas targeted for intensified MDRO control. Some facilities may choose to assign dedicated staff to targeted patient care areas to enhance consistency of proper environmental cleaning and disinfection services. <i>(IB)</i>	during limited period of time as a component of an intensified MRSA control program. <i>(II)</i>
Provide necessary leadership, funding, and day-to-day oversight to implement interventions selected. <i>(IB)</i>			Implement laboratory protocols for storing isolates or selected MDROs for molecular typing; perform typing if needed. <i>(IB)</i>	In LTCFs, modify CP to allow MDRO colonized/infected patients whose site of colonization or infection can be appropriately contained and who can observe good hand hygiene practices to enter common areas and participate in group activities.	Monitor cleaning performance to ensure consistent cleaning and disinfection of surfaces in close proximity to the patient and those likely to be touched by the patient and HCP (e.g., bed rails, carts, bedside commodes, doorknobs, faucet handles). <i>(IB)</i>	When decolonization for MRSA is used, perform susceptibility testing for the decolonizing agent against the target organism or the MDRO strain epidemiologically implicated in transmission. Monitor susceptibility to detect emergence of resistance to the decolonizing agent. Consult with microbiologists for appropriate resistance testing, since standards have not been established.
Evaluate healthcare system factors for role in creating or perpetuating MDRO transmission, including staffing levels, education and training, availability of consumable and durable resources, communication processes, and adherence to infection prevention measures. <i>(IB)</i> Update healthcare providers and administrators on the progress and effectiveness of the intensified interventions. <i>(IB)</i>			Develop and implement protocols to obtain active surveillance cultures from patients in populations at risk. <i>(IB)</i> (See recommendations for appropriate body sites and culturing methods.)	When active surveillance cultures are obtained as part of an intensified MDRO control program, implement CP until the surveillance culture is reported negative for the target MDRO. <i>(IB)</i>	Obtain environmental cultures (e.g., surfaces, shared equipment) only when epidemiologically implicated in transmission. <i>(IB)</i>	Do not use topical mupirocin routinely for MRSA decolonization of patients as a component of MRSA control programs in any healthcare setting. <i>(IB)</i>
			Conduct culture surveys to assess efficacy of intensified MDRO control interventions.	No recommendation is made for universal use of gloves and/or gowns. <i>(Unresolved issue)</i>	Vacate units for environmental assessment and intensive cleaning when previous efforts to control environmental transmission have failed. <i>(II)</i>	
			Conduct serial (e.g., weekly) unit-specific point-prevalence culture-surveys of the target MDRO to determine if transmission has decreased or ceased. <i>(IB)</i>	Implement policies for patient admission and placement as needed to prevent transmission of the problem MDRO. <i>(IB)</i>		Limit decolonization to HCP found to be colonized with MRSA who have been epidemiologically implicated in ongoing transmission of MRSA to patients. <i>(IB)</i>
			Repeat point-prevalence culture-surveys at routine intervals and at time of patient discharge or transfer until transmission has ceased. <i>(IB)</i>	When single-patient rooms are available, assign priority for these rooms to patients with known or suspected		No recommendation can be made for decolonization of patients who carry VRE or MDR-GNB.
			If indicated by assessment of the MDRO problem, collect cultures to assess the			

colonization status of roommates and other patients with substantial exposure to patients with known MDRO infection or colonization. *(IB)*

Obtain cultures from HCP for target MDROs when there is epidemiologic evidence implicating the staff member as a source of ongoing transmission. *(IB)*

MDRO colonization or infection. Give highest priority to those patients who have conditions that may facilitate transmission (e.g., uncontained secretions or excretions). When single-patient rooms are not available, cohort patients with the same MDRO in the same room or patient care area. *(IB)*

When cohorting patients with the same MDRO is not possible, place MDRO patients in rooms with patients who are at low risk for acquisition of MDROs and associated adverse outcomes from infection and are likely to have short lengths of stay. *(II)*

Stop new admissions to the unit or facility if transmission continues despite the implementation of the intensified control measures. *(IB)*

CP, Contact  
Precautions;  
ESBLs, extended-  
spectrum  $\beta$ -  
lactamases; HCP,  
healthcare  
personnel; LTCF,  
long-term care  
facilities; MDR-  
GNB, multidrug-  
resistant Gram-  
negative bacilli;  
MRSA,  
methicillin-  
resistant  
*Staphylococcus*  
*aureus*; VISA,  
vancomycin-  
intermediate *S.*  
*aureus*; VRE,  
vancomycin-  
resistant  
enterococci;  
VRSA,  
vancomycin-  
resistant *S.*  
*aureus*.

## Conclusions

Healthcare settings accommodate patients in a variety of facilities employing a vast assortment of HCP. Barrier precaution practices are the fundamental elements to prevent healthcare-associated infections (HAIs). However, the importance of human factors in decreasing transmission plays an additional role, and unique strategies are therefore needed to reduce the risk of associated infections. The increase in the prevalence of MDROs in facilities and the community creates new problems and challenges. Implementing an effective program and reassessing the effectiveness of the measures employed will maximize patient safety efforts to reduce HAIs.

## International Perspective

As global epidemics increase in frequency and gain media attention, healthcare facilities must be ready to respond to pandemic scenarios. Preparedness for pathogens such as novel coronaviruses (e.g., SARS-CoV and MERS-CoV) and pandemic influenza not only serve to educate HCP, but also serve as templates for containing other diseases that may emerge in the future.

Globalization has highlighted the need to "think globally" as facilities "act locally." Many exotic diseases, such as SARS and avian influenza, are only a plane ride away. The World Health Organization (WHO) is a global organization sanctioned out of the United Nations that is responsible for directing and coordinating global health concerns. Transnational infectious disease threats and epidemics can only be addressed successfully through a concerted global effort. Although the CDC directs infection prevention activities in the United States, the WHO publishes infection control guidelines that can be implemented in healthcare facilities worldwide. The collection of recommendations can be accessed at the following website and coupled with the CDC Isolation

Guidelines: <http://www.searo.who.int/entity/emergencies/documents/infectioncontrolfullmanual.pdf>.

WHO's global patient safety initiative includes hand hygiene as the leading measure to interrupt the transmission of HAIs. However, several studies suggest that promoting hand hygiene, especially with the use of alcohol hand rubs, may be challenged by religious and cultural beliefs surrounding alcohol. Strategies to promote hand hygiene in diverse cultures include consultation with local clergy, focus groups with questions and answers, and use of products with the least amount of alcohol odor.<sup>20</sup>

Healthcare providers should query patients about international travel if they exhibit respiratory symptoms suggestive of diseases such as avian influenza, novel coronaviruses, or novel H1N1 influenza. Obtaining a thorough travel history is particularly critical in the ambulatory setting, as this is the first opportunity for many healthcare facilities to appropriately triage and isolate incoming patients. HCP can recommend that the traveler seek advice from freestanding clinics that specialize in travel or log on to the CDC travel website (<http://www.cdc.gov/travel>).

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## Aseptic Technique

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### Abstract

*Following observations of Ignaz Semmelweis and others over 100 years ago, the practice of aseptic technique is an infection prevention method that is recognized as an important factor in the prevention and transmission of healthcare-associated infections.<sup>1</sup>Aseptic technique improves patient safety and prevents healthcare-associated infections that may negatively impact outcomes including: increasing patient morbidity and mortality, increasing healthcare costs for patients and their families, prolonging length of stay, increasing resistance of microorganisms to antimicrobials, and increasing physical and mental discomfort for the patient.<sup>2</sup>Aseptic techniques, defined as the process for keeping away disease-producing microorganisms, may be used in any clinical setting. Situations in which surgical asepsis technique is applied include surgery as well as other areas where invasive procedures are done such as placement of intravenous lines, urinary catheters, chest tubes, and any other indwelling devices. Clean technique, or medical asepsis, is another practice to prevent or reduce the risk of transmission of organisms from one person to another or from one place to another. Clean technique leads to a decrease of the overall number of microorganisms present rather than the absence of microorganisms as is found in surgical asepsis.<sup>3</sup>Insertion and maintenance of invasive devices are guided by published evidenced-based recommendations supporting education, training, and standardized care for patients with central lines, surgical sites, ventilators, and urinary catheters. Surgical and medical aseptic techniques encompass similar strategies such as hand hygiene but with distinct differences.*

## Key Concepts

- Asepsis is defined as the process for keeping away disease-producing microorganisms. It is implemented to protect the patient by minimizing contamination to reduce the risk for infection.
- Surgical asepsis is the use of sterile technique to prevent the transfer of any organisms from one person to another or from one body site to another. The goal of sterile technique is to maintain the microbe count at an irreducible minimum.<sup>3</sup>
- Medical asepsis, or clean technique, refers to practice interventions that reduce the numbers of microorganisms to prevent and reduce transmission risk from one person (or place) to another.<sup>3</sup>
- Hand hygiene refers to a variety of practices aimed at reducing the microbial flora on the hands. Examples include hand washing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis, maintenance of skin condition and fingernails, and wearing of jewelry.<sup>1</sup>
- An antiseptic agent is defined as an antimicrobial substance applied to the skin to reduce the number of microbial flora.

## Background

Prevention of healthcare-associated infections (HAIs) is a national priority. Leaders in healthcare organizations, professional associations, government and accrediting agencies, legislators, regulators, payers, and consumer advocacy groups as well as consumers that want implementation of evidence-based practices for prevention of HAIs and increased patient safety practices are scrutinizing published recommendations to address the prevention of common HAIs.<sup>4</sup> Microorganisms capable of causing illness in humans are transmitted by both direct and indirect contact. Interrupting transmission of microorganisms from reservoir to susceptible host can prevent these illnesses. The practice of asepsis is a key strategy for preventing this transmission.

## Basic Principles

Asepsis is a basic infection prevention method as well as an important factor in patient safety in all healthcare settings. Aseptic technique is adaptable in all practice settings to minimize the risk of infection transmission. This technique prevents contamination from person to person and from one body site to another. Surgical asepsis implies sterility and is applied to patients undergoing invasive procedures to prevent potential contamination of the operative or procedure field.

## Aseptic Technique

Aseptic technique refers to practices designed to render and maintain objects and areas maximally free from microorganisms and aid in the prevention of surgical site, urinary tract, bloodstream, and pneumonia infections that may be device- or procedure-related, including those associated with intravascular devices, urinary catheters, and indwelling drains or devices. Aseptic technique involves using barriers, such as sterile gloves, sterile gowns, masks, and sterile drapes, to prevent the transfer of microorganisms from care providers and the environment to the patient during the procedure being performed. Aseptic technique should always be performed when placing invasive devices. Other

components of aseptic technique include using appropriate attire, hand hygiene, skin antisepsis, appropriate use of sterile or clean devices, supplies and equipment, and environmental cleaning and disinfection. See Table 30-1.

The Centers for Disease Control and Prevention (CDC) recommends that sterile dressings be used for incisions that have been closed primarily for the first 24 to 48 hours postoperatively. The American College of Surgeons has recommended that sterile gloves be used for dressing changes performed during the first 24 hours after surgery. The use of sterile gloves should always be considered as a method for preventing the transfer of organisms to the wound site. An individual practice of the provider may include a double-gloving technique that involves removal of the gloves after the debridement before completion of dressing change.

## CLEAN TECHNIQUE

Clean technique refers to medical aseptic practices that use clean and disinfected or sterile equipment and supplies to reduce the numbers of microorganisms and minimize the risk of transmission from personnel or the environment to the patient. Clean gloves instead of sterile gloves may be worn after hand antisepsis in most instances where clean technique is indicated, although sterile gloves should be used for sterile dressing applications. The "no-touch" dressing technique should be used to prevent contamination of sterile dressings, depending on the type and extent of the procedure.<sup>3</sup> The use of nonsterile versus sterile gloves for routine changing of surgical site dressings, tracheostomy care, and maintenance of intravascular lines remains an unresolved issue because the site may be colonized and, therefore, not sterile.<sup>5,6,7</sup> Clean gloves may be used as long as the techniques used prevent the transfer of new organisms or movement from one site to another on the patient. A clean gown should be worn to minimize contamination of clothing following standard precaution guidelines. Application of clean technique includes the following situations: wound care, placement of intravascular devices such as peripheral venous catheters, and respiratory suctioning. In some settings such as home care, use of a clean urinary catheter and clean gloves may be acceptable for chronic intermittent self-catheterization.<sup>8</sup>

## SURGICAL ASEPTIC TECHNIQUE OUTSIDE OF THE OPERATING ROOM

Settings outside the operating room may not have the capacity to follow the same strict level of surgical asepsis applied in the operating room. However, the goal to avoid infection remains in all clinical settings. For example, a critically ill trauma patient or neonate may be too unstable for transport to the operating room. Procedures may be accomplished in a radiology suite with access to invasive imaging procedures or at the bedside. In these circumstances, using environmental controls to maximize the reduction of microorganisms during surgical procedures is essential. Such strategies may include the following: (1) use of special treatment or operating rooms, (2) managing activity to reduce airborne transmission if procedures are performed at the bedside, (3) keeping doors closed during procedures, (4) using physical barriers such as screens, (5) diverting traffic in open units, (6) excluding visitors and unnecessary personnel, (7) avoiding cleaning activities in the area during invasive procedures, and (8) providing additional environmental controls such as ventilation to further reduce contamination.<sup>1,3,5</sup> As always, it's important to determine whether or not these practices will comply with state regulatory requirements. Some practices may not require use of a sterile gown or sterile barriers; refer to your organization's policies and procedures.

## ASEPTIC TECHNIQUE FOR STERILE FIELDS IN THE OPERATING ROOM

Sterile technique is strictly adhered to in the operating room when maintaining the sterile field, or the area surrounding the site of the incision or perforation into tissue, or the site of introduction of an instrument into a body orifice that has been prepared for an invasive procedure. Barriers are to be used to decrease the risk of transmission from practitioner or environment to the patient by maintaining a sterile field with sterile drapes, sterile gloves, and sterile gowns. Sterile drapes and drape accessories are used to cover all working areas, furniture, and equipment and the personnel in the sterile field wear sterile attire.<sup>1</sup>

**Table 30-1** Examples of Suggested Techniques by Procedure

Procedure/ Intervention	Hand Hygiene Indicated	Type of Personal Protective Equipment to Be Used*	Supplies Indicated	Instrumentation
Wound cleaning	Yes	Clean exam gloves and personal protective equipment as appropriate	Normal saline or prepared sterile wound cleanser. Sterile supplies such as 4 × 4 or cotton applicators	Irrigation performed with sterile device while maintaining clean technique
Routine dressing changes without debridement	Yes	Clean exam gloves and personal protective equipment as appropriate	Sterile supplies using clean technique	Sterile supplies using clean technique
Dressing change with mechanical, chemical, or enzymatic debridement	Yes	Clean exam gloves and personal protective equipment as appropriate	Sterile supplies using clean technique	Sterile supplies using clean technique
Dressing change with sharp, conservative bedside debridement	Yes	Sterile gloves and personal protective equipment as appropriate	Sterile supplies and sterile technique due to the potential for entering new, unaffected tissues	Sterile supplies and sterile technique
Central line dressing change	Yes	Sterile gloves for removing old dressing and new sterile gloves for dressing change procedure	Sterile dressing change kit and sterile technique; surgeon mask should be worn	Sterile supplies and sterile technique
Tracheal suctioning where the tracheal suction catheter is not within a closed sheath	Yes	Sterile gloves, use of personal protective equipment, including face shield or mask when suctioning	Sterile suction catheter	Sterile supplies using clean technique
Tracheostomy care or suctioning with a suction catheter within a closed sheath	Yes	Clean exam gloves and use or personal protective equipment, including face shield or mask	Sterile supplies using clean technique	Sterile supplies using clean technique

\* The CDC and American College of Surgeons have recommended that sterile technique be used for dressing changes performed during the first 24 hours after surgery.<sup>5,11</sup> The use of sterile gloves should always be considered as a method for preventing the transfer of organisms to the wound site. An individual practice of the provider may include a double-gloving technique that involves removal of the gloves after the debridement before completion of dressing change.

In the surgical setting, a higher rate of air exchanges and maintenance of positive pressure in relation to the adjacent corridors or spaces is appropriate. Appropriate air duct filters are also required and need to be checked and changed at appropriate intervals. Temperature and humidity monitors and controls are also essential to maintain environmental controls in the operating room.<sup>1,9</sup>



## ATTIRE

Appropriate attire is based on the risk of the procedure and the area of the hospital where the procedure is performed. It is important to remember that scrubs are not considered personal protective equipment (PPE). Based on the amount of anticipated soilage, personnel performing procedures resulting in splashing or potential exposure to body fluids should wear impervious or fluid-resistant barriers as well as face and eye protection. Additionally, some aseptic procedures such as insertion of central lines require utilization of sterile gowns. Depending on the aseptic procedure being performed, barriers may include gloves, gowns, and hair covering (refer to your organization's policies and procedures).

Freshly laundered scrubs are worn in semirestricted and restricted zones in the surgical areas to prevent microbial contamination from shed skin squames and particulate (e.g., lint) transference to the sterile field, including the surgical site and patient. Additional attire (i.e., sterile gowns) may also be required to reduce risk of occupational exposure to bloodborne pathogens and other potentially infectious materials as well as to maintain the sterile field. Head and facial hair covering and clean shoes should also be worn in the semirestricted and restricted areas of the operating room. Masks should be worn in restricted areas when open sterile supplies and equipment are present.<sup>1</sup>

## HAND HYGIENE

Hand decontamination prior to any procedure is an integral step of the process that should be done by the team working in direct contact with the patient, equipment, instruments, and/or sterile field. Maximum reduction of skin microorganisms without damaging tissue is accomplished when healthcare providers decontaminate their hands using an antiseptic hand rub or antiseptic soap before operative procedures. In surgical areas, scrubbing should be performed before donning sterile gloves. Long natural fingernails, artificial fingernails, or any fingernail enhancements should not be worn by direct care providers of high-risk patients (i.e., intensive care unit, operating room, oncology, neonatal).<sup>1,2</sup>

## SKIN ANTISEPSIS

It is imperative to use the appropriate recommended antiseptic for each procedure type as well as screening for contraindications such as allergies and age limitations. Antiseptic agents should be used following manufacturers' directions for use, including ensuring the skin is clean before placement as well as antiseptic contact and drying time.<sup>1,3</sup>

## SINGLE-USE DEVICES, EQUIPMENT, AND SUPPLIES

Other aseptic practices involve using single-use devices and equipment or reusable devices and equipment that have been properly processed and packaged. Personnel should maintain the sterile packaging and/or container integrity to ensure an intact seal and confirm that sterilization indicators with expiration date (if provided) are verified. Before use, sterile packages should always be inspected for signs of contamination such as moisture, tears, or discoloration in addition to the expiration date. Items including solutions should be aseptically transferred to sterile fields.<sup>1</sup>

When used for sterile procedures, disinfectant pads or swabs (i.e., alcohol, chlorhexidine, betadine), including those in sterile kits or trays, should be checked to verify that the label on their package indicates they are sterile—otherwise, they are considered a nonsterile item.

## ENVIRONMENTAL CLEANING



Routine cleaning and disinfecting environmental surfaces with an Environmental Protection Agency (EPA)-approved hospital disinfectant detergent<sup>6</sup> and the use of an efficacious germicidal agent for cleanup of blood or body fluid spills are both examples of controlling the environment to reduce the risk of contamination and microbial transmission in all patient care settings. Use clean equipment and supplies (mops, water, cleaning cloths) for environmental hygiene. Most germicides recommend removing the original bioburden from the environment with cleaning agents and techniques followed by use of the germicide to disinfect the area.<sup>9</sup> Checklists for training and quality monitoring of operating room cleaning procedures are important training tools.<sup>10</sup>

Additional information and specific recommendations relative to the prevention of specific infections can be found in **33. Urinary Tract Infection**, **34. Intravascular Device Infection**, **35. Infections in Indwelling Medical Devices**, **37. Surgical Site Infection**, **68. Surgical Services**, and **106. Sterile Processing**.

## Conclusions

Aseptic technique can be performed in clinical practice areas that have adequate as well as limited resources.<sup>5</sup> Examples of asepsis that can reduce the potential risk of infection for the patient and healthcare personnel include: a clean environment, conscientious practicing of hand hygiene, use of appropriate personal protective equipment, and use of standardized routine cleaning, disinfection, and sterilization practices. All healthcare personnel should be cognizant of their movement, barrier use, and practices to prevent inadvertent breaks in aseptic technique.<sup>8,9</sup> Alerting others when the field or objects are potentially contaminated is essential to maintaining aseptic technique and improving patient safety and patient outcomes.

Breaches of infection prevention practices and aseptic technique contributing to cross-contamination that may lead to the transmission of infections between patients should be reported and investigated by the infection prevention team.

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## Cleaning, Disinfection, and Sterilization

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### Abstract

*All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semicritical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning must always precede high-level disinfection and sterilization.*

### Introduction

All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic

microbes leading to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (e.g., *Mycobacterium tuberculosis*–contaminated bronchoscopes). This chapter capsulizes other papers on this subject as well as provides updated information of newer sterilization (e.g., hydrogen peroxide vapor, ozone) and disinfection (e.g., improved hydrogen peroxide) technologies.<sup>1,2,3,4,5</sup>

## A Rational Approach to Disinfection and Sterilization

More than 45 years ago, Earle H. Spaulding<sup>6</sup> devised a rational approach to disinfection and sterilization of patient care items or equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.<sup>1,5,7,8,9</sup> Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into three categories based on the degree of risk of infection involved in the use of the items. The three categories he described were critical (enters sterile tissue and must be sterile), semicritical (contacts mucous membranes and requires high-level disinfection), and noncritical (comes in contact with intact skin and requires low-level disinfection). These categories and the methods to achieve sterilization, high-level disinfection, and low-level disinfection are summarized in Table 31-1. Although the scheme remains valid there are some examples of disinfection studies with viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high- and low-level disinfection.<sup>10</sup>

### CRITICAL ITEMS

Critical items are so called because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Thus, it is critical that objects that enter sterile tissue or the vascular system be sterile because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. The items in this category should be purchased as sterile or be sterilized by steam sterilization, if possible. If heat-sensitive, the object may be treated with ethylene oxide (ETO), hydrogen peroxide gas plasma, ozone, vaporized hydrogen peroxide, or by liquid chemical sterilants if other methods are unsuitable. Tables 31-1 to 31-3 list sterilization processes and liquid chemical sterilants. With the exception of 0.2 percent peracetic acid (12 minutes at 50° to 56°C), the indicated exposure times for liquid chemical sterilants range from 3 to 12 hours.<sup>11</sup> Liquid chemical sterilants can be relied upon to produce sterility only if cleaning, which eliminates organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met. Another limitation to sterilization of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in a liquid chemical sterilant, thus it is impossible to maintain sterility following processing and during storage. Furthermore, devices may require rinsing following exposure to the liquid chemical sterilant with water that, generally, is not sterile. Therefore, due to the inherent limitations of using liquid chemical sterilants in a nonautomated reprocessor, their use should be restricted to reprocessing critical devices that are heat-sensitive and incompatible with other sterilization methods.

### SEMICRITICAL ITEMS

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes,

esophageal manometry probes, anorectal manometry catheters, endocavitary probes (e.g., rectal and vaginal probes), prostate biopsy probes, infrared coagulation devices, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (i.e., mycobacteria, fungi, viruses, bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but are susceptible to other organisms such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, improved hydrogen peroxide, peracetic acid with hydrogen peroxide, and chlorine-based products are cleared by the U.S. Food and Drug Administration (FDA)<sup>11</sup> and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Tables 31-1 and 31-2). The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20° to 25°C. The reprocessing of semicritical items such as endoscopes, laryngoscopes, and nasopharyngoscopes are discussed in detail in a recent paper.

12

Since semicritical equipment has been associated with reprocessing errors that result in patient lookback and patient notifications, it is essential that control measures be instituted to prevent patient exposures.<sup>13,14</sup> Before new equipment (especially semicritical equipment as the margin of safety is less than that for sterilization)<sup>15</sup> is used for patient care on more than one patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested. Infection control rounds or audits should be conducted annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing standards and policies. Results of infection control rounds should be provided to the unit managers and deficiencies in reprocessing should be corrected and the corrective measures documented to infection control within 2 weeks.

**Table 31-1** Methods for Disinfection and Sterilization of Patient-Care Items and Environmental Surfaces

Process	Level of Microbial Inactivation	Method	Examples (with processing times)	Healthcare Application (examples)
Sterilization	Destroys all microorganisms, including bacterial spores	High temperature	Steam (~40 min), dry heat (1-6 hr depending on temperature)	Heat-tolerant critical (surgical instruments) and semicritical patient-care items
		Low temperature	Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min)	Heat-sensitive critical and semicritical patient-care items
		Liquid immersion	Chemical sterilants include*: >2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); >0.2% PA (12 min at 50-56°C)	Heat-sensitive critical and semicritical patient-care items that can be immersed

High-level disinfection (HLD)	Destroys all microorganisms except high numbers of bacterial spores	Heat-automated  Liquid immersion	Pasteurization (65-77°C, 30 min)  Chemical sterilants/HLDs include*: >2% glut (10-90 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 650-675 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)	Heat-sensitive semicritical items (e.g., respiratory therapy equipment)  Heat-sensitive semicritical items (e.g., GI endoscopes, bronchoscopes, endocavitary probes)
Intermediate-level disinfection	Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores	Liquid contact	EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (e.g., chlorine-based products, phenolics, improved hydrogen peroxide-exposure times at least 1 min)	Noncritical patient care item (blood pressure cuff) or surface with visible blood
Low-level disinfection	Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (e.g., chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood



Modified from various publications.<sup>4,8,163</sup>

\*Consult the FDA-cleared package insert for information about the cleared contact time and temperature, and see reference 1 for discussion on why one product is used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess (AER) will reduce the contact time (e.g., OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants above vary from 20° to 25°C; check FDA-cleared temperature conditions.<sup>11</sup> Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (e.g., HP and HP with PA will cause functional damage to endoscopes).

Abbreviations: glut, glutaraldehyde; HP, hydrogen peroxide; PA, peracetic acid; OPA, ortho-phthalaldehyde; ppm, parts per million; EPA, Environmental Protection Agency; FDA, Food and Drug Administration; GI, gastrointestinal.

**Table 31-2** Summary of Advantages and Disadvantages of Chemical Agents Used as Chemical Sterilants\* or as High-level Disinfectants

Sterilization Method	Advantages	Disadvantages
Peracetic acid/hydrogen peroxide	<ul style="list-style-type: none"><li>• No activation required</li><li>• Odor or irritation not significant</li></ul>	<ul style="list-style-type: none"><li>• Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional</li><li>• Limited clinical experience</li><li>• Potential for eye and skin damage</li></ul>

Glutaraldehyde	<ul style="list-style-type: none"> <li>• Numerous use studies published</li> <li>• Relatively inexpensive</li> <li>• Excellent material compatibility</li> </ul>	<ul style="list-style-type: none"> <li>• Respiratory irritation from glutaraldehyde vapor</li> <li>• Pungent and irritating odor</li> <li>• Relatively slow mycobactericidal activity (unless other disinfectants added such as phenolic, alcohol)</li> <li>• Coagulates blood and fixes tissue to surfaces</li> <li>• Allergic contact dermatitis</li> </ul>
Hydrogen peroxide	<ul style="list-style-type: none"> <li>• No activation required</li> <li>• May enhance removal of organic matter and organisms</li> <li>• No disposal issues</li> <li>• No odor or irritation issues</li> <li>• Does not coagulate blood or fix tissues to surfaces</li> <li>• Inactivates <i>Cryptosporidium</i></li> <li>• Use studies published</li> </ul>	<ul style="list-style-type: none"> <li>• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional</li> <li>• Serious eye damage with contact</li> </ul>
Ortho-phthalaldehyde (OPA)	<ul style="list-style-type: none"> <li>• Fast acting high-level disinfectant</li> <li>• No activation required</li> <li>• Odor not significant</li> <li>• Excellent materials compatibility claimed</li> <li>• Does not coagulate blood or fix tissues to surfaces claimed</li> </ul>	<ul style="list-style-type: none"> <li>• Stains protein gray (e.g., skin, mucous membranes, clothing, and environmental surfaces)</li> <li>• Limited clinical experience</li> <li>• More expensive than glutaraldehyde</li> <li>• Eye irritation with contact</li> <li>• Slow sporicidal activity</li> <li>• Anaphylactic reactions to OPA in bladder cancer patients with repeated exposure to OPA through cystoscopy</li> </ul>

Peracetic acid	<ul style="list-style-type: none"> <li>• Rapid sterilization cycle time (30-45 min)</li> <li>• Low temperature (50-55°C) liquid immersion sterilization</li> <li>• Environmental friendly by-products (acetic acid, O<sub>2</sub>, H<sub>2</sub>O)</li> <li>• Fully automated</li> <li>• Single-use system eliminates need for concentration testing</li> <li>• Standardized cycle</li> <li>• May enhance removal of organic material and endotoxin</li> <li>• No adverse health effects to operators under normal operating conditions</li> <li>• Compatible with many materials and instruments</li> <li>• Does not coagulate blood or fix tissues to surfaces</li> <li>• Sterilant flows through scope facilitating salt, protein, and microbe removal</li> <li>• Rapidly sporicidal</li> <li>• Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)</li> </ul>	<ul style="list-style-type: none"> <li>• Potential material incompatibility (e.g., aluminum anodized coating becomes dull)</li> <li>• Used for immersible instruments only</li> <li>• Biological indicator may not be suitable for routine monitoring</li> <li>• One scope or a small number of instruments can be processed in a cycle</li> <li>• More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection</li> <li>• Serious eye and skin damage (concentrated solution) with contact</li> <li>• Point-of-use system, no sterile storage</li> <li>• An AER using 0.2% peracetic acid not FDA-cleared as sterilization process but HLD</li> </ul>
Improved hydrogen peroxide (2.0%)	<ul style="list-style-type: none"> <li>• No activation required</li> <li>• No odor</li> <li>• Non-staining</li> <li>• No special venting requirements</li> <li>• Manual or automated applications</li> <li>• 12-month shelf life, 14-day reuse</li> <li>• 8 min at 20°C high-level disinfectant claim</li> </ul>	<ul style="list-style-type: none"> <li>• Material compatibility concerns due to limited clinical experience</li> <li>• Organic material resistance concerns due to limited data</li> </ul>

Modified from several papers.<sup>1,3,4,164,165</sup>

\*All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.

Abbreviations: AER, automated endoscope reprocessor; FDA, U.S. Food and Drug Administration; HLD, high-level disinfectant.

## NONCRITICAL ITEMS

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." Examples of noncritical items are bedpans, blood pressure cuffs, crutches, bed rails, linens, bedside tables, patient furniture, and floors. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. There is virtually no documented risk of transmitting infectious agents to patients via noncritical items<sup>16</sup>when they are used as noncritical items and do not contact nonintact skin and/or mucous membranes. However, these items (e.g., bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of healthcare personnel or by contact with medical equipment that will subsequently come in contact with patients.<sup>17</sup>Table 31-1 lists several low-level disinfectants that may be used for noncritical items. The exposure time for low-level disinfection of noncritical items is at least 1 minute.

**Table 31-3** Summary of Advantages and Disadvantages of Commonly Used Sterilization Technologies

Sterilization Method	Advantages	Disadvantages
Steam	<ul style="list-style-type: none"> <li>• Nontoxic to patient, staff, environment</li> <li>• Cycle easy to control and monitor</li> <li>• Rapidly microbicidal</li> <li>• Least affected by organic/inorganic soils among sterilization processes listed</li> <li>• Rapid cycle time</li> <li>• Penetrates medical packing, device lumens</li> </ul>	<ul style="list-style-type: none"> <li>• Deleterious for heat-sensitive instruments</li> <li>• Microsurgical instruments damaged by repeated exposure</li> <li>• May leave instruments wet, causing them to rust</li> <li>• Potential for burns</li> </ul>
Hydrogen peroxide gas plasma	<ul style="list-style-type: none"> <li>• Safe for the environment</li> <li>• Leaves no toxic residuals</li> <li>• Cycle time is ≥28 minutes and no aeration necessary</li> <li>• Used for heat- and moisture-sensitive items since process temperature &lt;50°C</li> <li>• Simple to operate, install (208 V outlet), and monitor</li> <li>• Compatible with most medical devices</li> <li>• Only requires electrical outlet</li> </ul>	<ul style="list-style-type: none"> <li>• Cellulose (paper), linens, and liquids cannot be processed</li> <li>• Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer's recommendations)</li> <li>• Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray</li> <li>• Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA</li> </ul>
100% Ethylene oxide (ETO)	<ul style="list-style-type: none"> <li>• Penetrates packaging materials, device lumens</li> <li>• Single-dose cartridge and negative- pressure chamber minimizes the potential for gas leak and ETO exposure</li> <li>• Simple to operate and monitor</li> <li>• Compatible with most medical materials</li> </ul>	<ul style="list-style-type: none"> <li>• Requires aeration time to remove ETO residue</li> <li>• ETO is toxic, a carcinogen, and flammable</li> <li>• ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO<sub>2</sub> and H<sub>2</sub>O</li> <li>• ETO cartridges should be stored in flammable liquid storage cabinet</li> <li>• Lengthy cycle/aeration time</li> </ul>

ETO mixtures 8.6% ETO/91.4% HCFC10% ETO/90% HCFC 8.5% ETO/91.5% CO <sub>2</sub>	<ul style="list-style-type: none"> <li>• Penetrates medical packaging and many plastics</li> <li>• Compatible with most medical materials</li> <li>• Cycle easy to control and monitor</li> </ul>	<ul style="list-style-type: none"> <li>• Some states (e.g., CA, NY, MI) require ETO emission reduction of 90-99.9%</li> <li>• CFC (inert gas that eliminates explosion hazard) banned in 1995</li> <li>• Potential hazards to staff and patients</li> <li>• Lengthy cycle/aeration time</li> <li>• ETO is toxic, a carcinogen, and flammable</li> </ul>
Vaporized hydrogen peroxide	<ul style="list-style-type: none"> <li>• Safe for the environment and health care worker</li> <li>• It leaves no toxic residue; no aeration necessary</li> <li>• Fast cycle time, 55 min</li> <li>• Used for heat and moisture sensitive items (metal and nonmetal devices)</li> </ul>	<ul style="list-style-type: none"> <li>• Medical devices restrictions based on lumen internal diameter and length—see manufacturer's recommendations, e.g., stainless steel lumen 1 mm diameter, 125 mm length</li> <li>• Not used for liquid, linens, powders, or any cellulose materials</li> <li>• Requires synthetic packaging (polypropylene)</li> <li>• Limited materials compatibility data</li> <li>• Limited clinical use and comparative microbicidal efficacy data</li> </ul>
Ozone	<ul style="list-style-type: none"> <li>• Used for moisture and heat-sensitive items</li> <li>• Ozone generated from oxygen and water (nontoxic)</li> <li>• No aeration needed due to no toxic by-products</li> <li>• FDA cleared for metal and plastic instruments including some instruments with lumens</li> </ul>	<ul style="list-style-type: none"> <li>• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbicidal efficacy data</li> </ul>
<p>Modified from several papers.<sup>3,4,165,166</sup></p> <p>Abbreviations: ETO, ethylene oxide; CFC, chlorofluorocarbon; HCFC, hydrochlorofluorocarbon; FDA, U.S. Food and Drug Administration; TWA, time-weighted average.</p>		

## Cleaning

Items must be cleaned using water with detergents or enzymatic cleaners before processing. Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent.<sup>18,19,20,21,22,23</sup> Cleaning is the removal of foreign material (e.g., soil, organic material) from objects, and it is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization since inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if the soiled materials become dried or baked onto the instruments the removal process becomes more difficult and the disinfection or sterilization process becomes less effective or ineffective. Surgical instruments should be presoaked or rinsed to prevent drying of blood and to soften or remove blood from the instruments.

Instrument cleaning is done manually when the use area does not have a mechanical unit (e.g., ultrasonic cleaner, or washer-disinfector) or for fragile or difficult-to-clean instruments. If cleaning is done manually, the two essential components are friction and fluidics. Using friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow the passage of a brush through a channel.<sup>24</sup> When using a washer-disinfector, care should be taken as to the method of loading instruments. Hinged instruments should be opened fully to allow adequate contact with the detergent solution. The stacking of instruments in washers should be avoided. Instruments should be disassembled as much as possible.

The most common types of mechanical or automatic cleaners include ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Ultrasonic cleaning removes soil by a process called cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Bacterial contamination may be present in used ultrasonic cleaning solutions (and other used detergent solutions) as these solutions generally do not make antibacterial label claims.<sup>25</sup> While ultrasound alone does not cause significant inactivation of bacteria, sonication can act synergistically to increase the cidal efficacy of a disinfectant.<sup>26</sup> Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments that could cause severe inflammatory reactions.<sup>27</sup> Washer-sterilizers are modified steam sterilizers that clean by filling the chamber with water and detergent through which steam is passed to provide agitation. Instruments are subsequently rinsed and subjected to a short steam sterilization cycle. Another washer-sterilizer employs rotating spray arms for a wash cycle followed by a steam sterilization cycle at 285°F.<sup>28,29</sup> Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93°C for 10 minutes).<sup>30</sup> Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment. In one study, cleaning (measured as 5- to 6-log<sub>10</sub> reduction) was achieved on surfaces that were adequately in contact with the water flow in the machine.<sup>31</sup> Detailed information on cleaning and preparation of supplies for terminal sterilization is provided by professional organizations<sup>32,33</sup> and books.<sup>34</sup> Studies have shown that manual and mechanical cleaning of endoscopes achieves a 4- to 6-log<sub>10</sub> reduction of contaminating organisms.<sup>19,21,35,36</sup> Thus, cleaning alone is very effective in reducing the number of microorganisms present on contaminated equipment. When manual methods are compared to automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures, the automated method was more efficient and achieved a more than 99 percent reduction in soil parameters (i.e., protein, carbohydrate, hemoglobin) in both ported and nonported laparoscopic devices.<sup>37</sup>

The choice for instrument cleaning is neutral or near-neutral pH detergent solutions, as these solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, are sometimes added to neutral pH solutions to assist in the removal of organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solution also can contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants and proteinaceous enzymes may be inactivated by germicides. Like all chemicals, enzymes must be rinsed from the equipment or adverse reactions

(e.g., fever) could result.<sup>38</sup> Enzyme solutions should be used in accordance with manufacturer's instructions. Detergent enzymes may be associated with asthma or other allergic effects in users. Neutral pH detergent solutions that contain enzymes are compatible with metals and other materials used in medical instruments and are the best choice for cleaning delicate medical instruments, especially flexible endoscopes.<sup>19</sup> Alkaline-based cleaning agents are used for processing medical devices as they dissolve protein and fat residues efficiently;<sup>39</sup> however, they may be corrosive.<sup>19</sup> Some data demonstrate that enzymatic cleaners are more effective cleaners than neutral detergents<sup>40-41</sup> in removing microorganisms from surfaces but two studies found no difference in cleaning efficiency between enzymatic and alkaline-based cleaners.<sup>39-42</sup> A new nonenzyme, hydrogen peroxide-based formulation was as effective as an enzymatic cleaner in removing protein, blood, carbohydrate, and endotoxin from surface test carriers.<sup>43</sup> In addition, this product was able to effect a 5-log<sub>10</sub> reduction in microbial loads with a 3-minute exposure at room temperature.<sup>43</sup> Validation of the cleaning processes in a laboratory testing program is possible by microorganism detection, chemical detection for organic contaminants (e.g., protein), radionuclide tagging, and chemical detection for specific ions.<sup>18-44</sup> Data have been published describing the use of an artificial soil, protein, endotoxin, x-ray contrast medium, or blood to verify the manual or automated cleaning process<sup>31-45,46,47,48,49</sup> and adenosine triphosphate (ATP) bioluminescence, fluorescence, and microbiologic sampling to evaluate the effectiveness of environmental surface cleaning.<sup>50,51,52</sup> Although ATP has been used to assess manual cleaning adequacy of flexible endoscope channels,<sup>53</sup> it has not been supported by epidemiological data to reduce infection risk or levels of microbial contamination that can cause disease. Minimally, all instruments should be individually inspected and be visibly clean.

## HOW CLEAN IS CLEAN?

The Association for the Advancement of Medical Instrumentation (AAMI) has proposed the use of < 6.4 µg/cm<sup>2</sup> as the benchmark for residual protein on medical and surgical instruments following cleaning of an instrument prior to sterilization. While there have been experiments that demonstrate the effectiveness of cleaning in eliminating or reducing many components of soil (e.g., protein, carbohydrate, hemoglobin, endotoxin, microorganisms),<sup>44-54</sup> investigators have not assessed if the components of soil (e.g., protein) that remain on the instrument interferes with sterilization or poses a risk of infection to patients.<sup>44-55,56,57,58</sup> In addition, there are no "real time" tests that can be performed in central processing areas that reliably determine a certain protein load (< 6.4 µg/cm<sup>2</sup>). While the presence of residual protein can be quantitatively assessed by many methods (e.g., ninhydrin, OPA method, chemical analysis, microbicinchoninic acid test kit) none of these methods can be applied to determine protein residues in central processing by staff.<sup>59</sup>

Additionally, before a test soil component (e.g., protein) is accepted as a good component for monitoring the cleaning efficacy of manual and automated washers, three other criteria should be met. First, the soil component should be achievable using standard cleaning protocols and manufacturer's instructions for use using a wide range of surgical instruments. Very few studies have measured the soil load on surgical instruments and the studies done have been done in a research setting by research staff.<sup>44-54</sup>

This is a significant consideration because North American hospitals do not conduct analytical monitoring of cleaning efficacy of instruments and do not know if the criteria set for soil are achievable.<sup>60</sup> Second,



the soil load on surgical instruments has not been sufficiently characterized to assess both the concentration and whether another component of soil is a better marker of cleaning efficacy and sterilization failure. For example, Alfa and colleagues found that the level of carbohydrate and endotoxin on instruments post cleaning was higher than that detected immediately after the patient procedure before cleaning.<sup>60</sup> Is protein the best marker of cleaning adequacy or are endotoxin, total organic carbon, carbohydrate, and/or hemoglobin more relevant parameters? Third, there are no scientific studies that demonstrate that protein load greater than 6.4 µg/cm<sup>2</sup> interferes with steam sterilization or poses an infection risk to patients. Further studies are needed to answer these important questions.

## CLEANING THROUGH LOCAL VERSUS CENTRAL REPROCESSING AREAS

The cleaning stage of instrument reprocessing has come under increased scrutiny due to the complexity of surgical instruments and the recognition that cleaning in local decontamination units may not be comparable to reprocessing in central processing areas. In general, central processing areas offer several advantages to include validated and specialized reprocessing equipment (e.g., washer-disinfectors) and persons that specialize in instrument reprocessing (preferably certified instrument reprocessing technicians). Local reprocessing offers the advantages of faster instrument turnaround, less instrument loss, and lower instrument inventory. In one study, instruments reprocessed by the central decontamination unit (median, 21 µg/instrument) had significantly less residual protein than instruments reprocessed by the local decontamination unit (median, 117 µg/instrument).<sup>61</sup>

## BIOFILMS

Microorganisms may be protected from disinfectants due to the production of thick masses of cells<sup>62</sup> and extracellular materials or biofilms.<sup>63,64,65,66,67,68,69,70,71</sup> Biofilms are microbial masses attached to surfaces that are immersed in liquids. Once these masses are formed, microbes may be resistant to the disinfectants by multiple mechanisms including higher resistance of older biofilms, genotypic variation of the bacteria, microbial production of neutralizing enzymes, and physiologic gradients within the biofilm (e.g., pH). Bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than the same bacteria in suspension.<sup>72</sup> Although new decontamination methods<sup>73</sup> are being investigated for removal of biofilms, chlorine and monochloramines are effective for inactivation of biofilm bacteria.<sup>65,74</sup> Investigators have hypothesized that the glycocalyx-like cellular masses on the interior walls of polyvinyl chloride pipe would protect embedded organisms from some disinfectants and serve as a reservoir for continuous contamination.<sup>63,64,75</sup> Biofilms have been found in whirlpools,<sup>76</sup> dental unit waterlines,<sup>77</sup> and numerous medical devices (e.g., contact lenses, pacemakers, hemodialysis systems, urinary catheters, central venous catheters, endoscopes).<sup>68,72,74,78</sup> Their presence may have serious implications for immunocompromised patients and patients with indwelling medical devices. Some enzymes<sup>42,72,79</sup> and detergents<sup>72,80</sup> can be used for the degradation of biofilms or reduction in viable bacterial numbers, but no products are registered by the Environmental Protection Agency (EPA) or cleared by the FDA for this purpose. One study evaluating the clearance effect of enzymatic and nonenzymatic detergents against *Escherichia coli* biofilms on the inner surface of gastroscopes found that nonenzymatic detergents and high-speed lavage (250 mL/min) are both important in temporal-formed biofilm elimination.<sup>81</sup>

In general, the available data suggest that by ensuring prompt device cleaning and reprocessing by either high-level disinfection or sterilization, biofilms will not have a chance to form.<sup>71</sup> However, biofilms

can develop inside channels if established protocols are not met and these biofilms can be difficult to remove.<sup>70</sup>

## TOXIC ANTERIOR SEGMENT SYNDROME

Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS and includes impurities of autoclave steam, heat stable endotoxin, and irritants on the surfaces of intraocular surgical instruments. General principles of cleaning and sterilizing intraocular surgical instruments have been published.<sup>82</sup>

## Current Issues and New Technologies In Disinfection and Sterilization

### HUMAN PAPILLOMA VIRUS

Emerging pathogens are of growing concern to the general public and infection prevention and control professionals. Human papilloma virus (HPV) is an extremely common sexually acquired infection and is considered the cause of cervical cancer. A recent study showed that a considerable number of ultrasound probes are contaminated with HPV (28 percent pre-examination).<sup>83</sup> While there are limited data regarding the inactivation of HPV by disinfectants because in vitro replication of complete virions has only been achieved recently, a pseudotype HPV-16 and a bovine papilloma virus were used in an infectivity assay to evaluate potential methods of disinfecting HPV-contaminated surfaces.<sup>84</sup> In this study, the bovine papilloma virus demonstrated substantial sensitivity to 70 percent ethanol and all infectivity was eliminated for pseudotype HPV-16 virions. Endovaginal ultrasound probes are semicritical items (even if covered with a sheath or probe cover) and require high-level disinfection.

### INACTIVATION OF CREUTZFELDT-JAKOB DISEASE AGENT

Creutzfeldt-Jakob disease (CJD) is a degenerative neurologic disorder of humans with an incidence in the United States of approximately 1 case/million population/year.<sup>85,86</sup> CJD is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs) that include kuru (0 incidence, now eradicated), Gerstmann-Strussler-Scheinker (GSS) syndrome (1/40 million), and fatal insomnia syndrome (FFI) (< 1/40 million). The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Since the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both conservative and controversial for many years.<sup>87,88</sup>

The current recommendations consider inactivation data but also use epidemiological studies of prion transmission, infectivity of human tissues, and efficacy of removing proteins by cleaning.<sup>85,87,88</sup> On the basis of scientific data, only critical (e.g., surgical instruments) and semicritical devices contaminated with high-risk tissue (i.e., brain, spinal cord, and eye tissue) from high-risk patients (e.g., known or suspected infection with CJD or other prion disease) require special prion reprocessing. A moist environment post contamination reduces the attachment of both protein and prion amyloid to the

stainless steel surface, so maintain moist conditions.<sup>89</sup>After the device is clean, it should be sterilized by either autoclaving (i.e., steam sterilization) or using a combination of sodium hydroxide and autoclaving using one of the following options:<sup>85</sup>(1) autoclave at 134°C for 18 minutes in a prevacuum sterilizer; (2) autoclave at 132°C for 1 hour in a gravity displacement sterilizer<sup>1'85'91</sup>; (3) immerse in 1N NaOH for 1 hour, remove and rinse in water, then transfer to an open pan and autoclave (121°C gravity displacement or 134°C porous or prevacuum sterilizer for 1 hour); or (4) immerse in 1N NaOH for 1 hour and heat in a gravity displacement at 121°C for 30 minutes, then clean and subject to routine sterilization. Some data suggest the temperature should not exceed 134°C since the effectiveness of autoclaving may decline as the temperature is increased (e.g., 136°C, 138°C).<sup>92</sup>Prion-contaminated medical devices that are impossible or difficult to clean should be discarded. To minimize environmental contamination, noncritical environmental surfaces should be covered with plastic-backed paper, and when contaminated with high-risk tissues, the paper should be properly discarded. Noncritical environmental surfaces (e.g., laboratory surfaces) contaminated with high-risk tissues should be cleaned and then spot decontaminated with a 1:10 dilution of hypochlorite solutions.<sup>85</sup>

## IMPROVED HYDROGEN PEROXIDE

An improved hydrogen peroxide-based technology has been introduced into healthcare for disinfection of noncritical environmental surfaces and patient equipment<sup>93</sup>and high-level disinfection of semicritical equipment such as endoscopes.<sup>94,95,96</sup>Improved hydrogen peroxide contains very low levels of anionic and/or nonionic surfactants in an acidic product that act with hydrogen peroxide to produce microbicidal activity. This combination of ingredients speeds the antimicrobial activity of hydrogen peroxide and cleaning efficiency.<sup>95'96</sup>Improved hydrogen peroxide is considered safe for humans and equipment, and benign for the environment. In fact, improved hydrogen peroxide has the lowest EPA toxicity category (i.e., category IV) based on its oral, inhalation, and dermal toxicity which means it is practically nontoxic and is not an irritant.<sup>93'95'97</sup>It is prepared and marketed by several companies in various concentrations (e.g., 0.5 to 7 percent) and different products may use different terminology for these products such as "accelerated" or "activated." Lower concentrations (i.e., 0.5 percent, 1.4 percent) are designed for the low-level disinfection of noncritical environmental surfaces and patient care objects while the higher concentrations (e.g., 2 percent) can be used as high-level disinfectants for semicritical medical devices (e.g., endoscopes).

A recent study compared the bactericidal activity of a quaternary ammonium compound to two new improved hydrogen peroxide products. The improved hydrogen peroxide products were superior or similar to the quaternary ammonium compound tested. When the two improved hydrogen peroxide products were compared to standard 0.5, 1.4, and 3 percent hydrogen peroxide formulations, the improved hydrogen peroxide-based environmental surface disinfectants proved to be more effective (> 6-log<sub>10</sub> reduction) and fast-acting (1 minute) microbicides in the presence of a soil load (to simulate the presence of body fluids) than commercially available hydrogen peroxide. Only 1 minute contact time was studied because longer contact times (e.g., 10 minutes) are not achievable in clinical practice. Additionally, the improved hydrogen peroxide products have an EPA-registered contact time that is substantially less (e.g., 30 seconds, 1 minute for bacteria) than most EPA-registered low-level disinfectants.<sup>98</sup>We have also recently shown that the 1.4 percent activated hydrogen peroxide is very effective in reducing microbial contamination of hospital privacy curtains (Rutala, Gergen, Weber, 2012, unpublished data). In our study, the activated hydrogen peroxide completely eliminated contamination

with methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE) and resulted in a 98.5 percent reduction in microbes (only *Bacillus* spp. recoverable). Thus, at UNC Health Care privacy curtains are being disinfected at the grab area by spraying the grab area of the curtain three times with activated hydrogen peroxide at discharge cleaning.

## REPROCESSING OF ENDOSCOPES

Physicians use endoscopes to diagnose and treat numerous medical disorders. While endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported as very low (about 1 in 1.8 million procedures),<sup>99</sup> some investigators believe that number is inaccurate and based on flawed methodology.<sup>100</sup> Clearly, more healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical or surgical device.<sup>101,102,103,104,105</sup> In order to prevent the spread of healthcare-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and at a minimum subjected to high-level disinfection following each use. High-level disinfection can be expected to destroy all microorganisms; although when high numbers of bacterial spores are present, a few spores may survive.

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed.<sup>1106,107,108,109</sup> Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing<sup>110,111,112,113</sup> and outbreaks of infection continue to occur.<sup>105</sup> In order to ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who is involved in reprocessing endoscopic instruments.<sup>1106,114,115</sup> Automated endoscope reprocessors can automate and standardize several important reprocessing steps and reduce the likelihood that an essential reprocessing step will be skipped and reduce personnel exposure to high-level disinfectants.<sup>1116</sup>

In general, endoscope disinfection or sterilization with a liquid chemical sterilant or high-level disinfectant involves five steps after leak testing: (1) *clean*, mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and an enzymatic cleaner; (2) *disinfect*, immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products; (3) *rinse*, rinse the endoscope and all channels with sterile water, filtered water (commonly used with automated endoscope reprocessors), or tap water; (4) *dry*, rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage; and (5) *store*, store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically).

Unfortunately, there is poor compliance with the recommendations for reprocessing endoscopes which may result in patient exposure to bloodborne pathogens.<sup>13,117</sup> In addition, there are rare instances where the scientific literature and recommendations from professional organizations regarding the use of disinfectants and sterilants may differ from the manufacturer's label claim. One example is the contact time used to achieve high-level disinfection with 2 percent glutaraldehyde. Based on FDA requirements (FDA regulates liquid sterilants and high-level disinfectants used on critical and semicritical medical devices), manufacturers test the efficacy of their germicide formulations under worse-case conditions (i.e., minimum recommended concentration of the active ingredient) and in the presence of organic soil



(typically 5 percent serum). The soil is used to represent the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. These stringent test conditions are designed to provide a margin of safety by assuring that the contact conditions for the germicide provide complete elimination of the test bacteria (e.g.,  $10^5$  to  $10^6$  *M. tuberculosis* in organic soil and dried on a scope) if inoculated into the most difficult areas for the disinfectant to penetrate and in the absence of cleaning. However, the scientific data demonstrate that *M. tuberculosis* levels can be reduced by at least 8-log<sub>10</sub> with cleaning (4-log<sub>10</sub>) followed by chemical disinfection for 20 minutes at 20°C (4- to 6-log<sub>10</sub>).<sup>1,21,107</sup> Because of these data, professional organizations (at least 14 professional organizations worldwide) that have endorsed an endoscope reprocessing guideline recommend contact conditions of 20 minutes at 20°C (or less than 20 minutes outside the United States) with 2 percent glutaraldehyde to achieve high-level disinfection that differs from that of the manufacturer's label.<sup>107,118,119,120</sup> It is important to emphasize that the FDA tests do not include cleaning, a critical component of the disinfection process. Therefore, when cleaning has been included in the test methodology, 2 percent glutaraldehyde for 20 minutes has been demonstrated to be effective in eliminating all vegetative bacteria.

## ROLE OF SURFACES IN DISEASE TRANSMISSION

There is excellent evidence in the scientific literature that environmental contamination plays an important role in the transmission of several key healthcare-associated pathogens including MRSA, VRE, *Acinetobacter*, norovirus, and *Clostridium difficile*.<sup>121,122,123,124,125</sup> All these pathogens have been demonstrated to persist in the environment for days (in some cases months), frequently contaminate the environmental surfaces in rooms of colonized or infected patients, transiently colonize the hands of healthcare personnel, be transmitted by healthcare personnel, and cause outbreaks in which environmental transmission was deemed to play a role. Importantly, a recent study by Stiefel and colleagues demonstrated that contact with the environment was just as likely to contaminate the hands of healthcare personnel as was direct contact with the patient.<sup>126</sup> Further, admission to a room in which the previous patient had been colonized or infected with MRSA, VRE, *Acinetobacter*, or *C. difficile*, has been shown to be a risk factor for the newly admitted patient to develop colonization or infection.<sup>127,128</sup>

## Adequacy of Room Cleaning and Disinfection Using Chemical Germicides

It has long been recommended in the United States that environmental surfaces in patient rooms be cleaned and disinfected on a regular basis (e.g., daily, three times per week), when surfaces are visibly soiled, and following patient discharge (terminal cleaning).<sup>1</sup> Disinfection is generally performed using an EPA-registered hospital disinfectant such as a quaternary ammonium compound. Recent studies have demonstrated that adequate environment cleaning is frequently lacking. For example, Carling and coworkers assessed the thoroughness of terminal cleaning in the patient's immediate environment in 23 acute care hospitals (1,119 patient rooms) by using a transparent, easily cleaned, stable solution that fluoresces when exposed to handheld ultraviolet (UV) light.<sup>129</sup> The overall thoroughness of cleaning, expressed as a percent of surfaces evaluated, was 49 percent (range for all hospitals, 35 to 81 percent). Using a similar design, Carling and associates assessed the environmental cleaning in intensive care unit rooms in 16 hospitals (2,320 objects) and demonstrated that only 57.1 percent of sites were cleaned following discharge of the room's occupant.<sup>130</sup> A recent study using ATP bioluminescence assays and aerobic cultures demonstrated that medical equipment frequently had not been disinfected as per protocol.<sup>131</sup>

## Improving Room Cleaning and Disinfection

Investigators have reported that intervention programs aimed at environmental services workers resulted in significant improvement in cleaning practices.<sup>52,132</sup> Such interventions have generally included multiple activities: improved education, monitoring the thoroughness of cleaning (e.g., by use of ATP assays or fluorescent dyes) with feedback of performance to the environmental service workers, and/or use of cleaning checklists. We have found that assignment of cleaning responsibility (e.g., medical equipment to be cleaned by nursing; environmental surfaces to be cleaned by environmental service) is also important to ensure all objects and surfaces are decontaminated, especially the surfaces of medical equipment (e.g., cardiac monitors). Improved environmental cleaning has been demonstrated to reduce the environmental contamination with VRE,<sup>133,134</sup> MRSA,<sup>134</sup> and *C. difficile*.<sup>135</sup> Importantly, no study has reported in the postintervention period, proper cleaning of more than 85 percent of objects. Further, all studies have only focused improvement on a limited number of "high risk" objects. Thus, a concern of published studies is that they have only demonstrated improved cleaning of a limited number of "high-risk" objects (or "targeted" objects) not an improvement in the overall thoroughness of room decontamination.

## Does Improved Surface Cleaning and Disinfection Reduce Healthcare-associated Infections?

Donskey recently performed a systematic review of the impact of environmental surface disinfection interventions on the incidence of healthcare-associated infections. He concluded that during the past decade a growing body of evidence has accumulated suggesting that improvements in environmental disinfection (e.g., product substitutions, education plus monitoring and feedback, enhanced cleaning, such as twice daily) may prevent transmission of pathogens and reduce healthcare-associated infections. Although the quality of much of the evidence remains suboptimal, a number of high-quality investigations now support environmental disinfection as a control strategy.<sup>136</sup>

## "NO TOUCH" METHODS FOR ROOM DECONTAMINATION

As noted above, multiple studies have demonstrated that environmental surfaces and objects in rooms are frequently not properly cleaned and these surfaces may be important in transmission of healthcare-associated pathogens. Further, while interventions aimed at improving cleaning thoroughness have demonstrated effectiveness, many surfaces remain inadequately cleaned and therefore potentially contaminated. For this reason, several manufacturers have developed room disinfection units that can decontaminate environmental surfaces and objects. These systems use one of two methods: either UV light or hydrogen peroxide.<sup>124</sup> These technologies supplement, but do not replace, standard cleaning and disinfection because surfaces must be physically cleaned of dirt and debris.

## Ultraviolet Light for Room Decontamination

UV irradiation has been used for the control of pathogenic microorganisms in a variety of applications, such as control of legionellosis, as well as disinfection of air, surfaces, and instruments.<sup>4,137</sup> At certain wavelengths, UV light will break the molecular bonds in DNA, thereby destroying the organism. UV-C has a characteristic wavelength of 200 to 270 nm (e.g., 254 nm), which lies in the germicidal active portion of the electromagnetic spectrum of 200 to 320 nm. The efficacy of UV irradiation is a function of many different parameters such as intensity, exposure time, lamp placement, and air movement patterns.



An automated mobile UV-C unit has been shown to eliminate  $> 3\text{-log}_{10}$  vegetative bacteria (MRSA, VRE, *Acinetobacter baumannii*) and  $> 2.4\text{-log}_{10}$  *C. difficile* seeded onto formica surfaces in patients' rooms experimentally contaminated.<sup>138</sup> Boyce and colleagues report the results of assessing the effectiveness of the same UV-C unit to reduce environmental contamination with vegetative bacteria (measured using aerobic colony counts) and *C. difficile* inoculated onto stainless steel carrier disks.<sup>139</sup> Room decontamination with the UV system resulted in significant reductions in aerobic bacteria on five high-touch surfaces. Mean  $\log_{10}$  *C. difficile* reductions ranged from 1.8 to 2.9 using cycle times of 34.2 to 100.1 minutes. Nerandzic and colleagues showed that UV-C at a reflected dose of 22,000 mWs/cm<sup>2</sup> for approximately 45 minutes consistently reduced recovery of *C. difficile* spores and MRSA by  $> 2\text{- to }3\text{-log}_{10}$  colony forming units (CFU)/cm<sup>2</sup> and of VRE by  $> 3\text{- to }4\text{-log}_{10}$  CFU/cm<sup>2</sup>.<sup>140</sup> Thus, there are now three studies that have demonstrated that a UV-C system is capable of reducing vegetative bacteria inoculated on a carrier by  $> 3\text{- to }4\text{-log}_{10}$  in 15 to 20 minutes and *C. difficile* by  $> 1.7\text{- to }4\text{-log}_{10}$  in 35 to 100 minutes. The studies also demonstrate reduced effectiveness when surfaces were not in direct line-of-sight.<sup>138,139,140</sup> Investigators have also demonstrated the effectiveness of an automated UV-C emitter against VRE, MRSA, *Acinetobacter* spp., and *C. difficile* in patient rooms<sup>138 141</sup> and use of a nanostructured UV-reflective wall coating significantly reduced the time (from 25 minutes to 5 minutes for MRSA and from 44 minutes to 9 minutes for *C. difficile* spores) necessary to decontaminate a room using a UV-C-emitting device.<sup>142</sup> A handheld far UV radiation device was tested and found to rapidly kill *C. difficile* spores and other healthcare-associated pathogens on surfaces. However, the presence of organic matter reduces the efficacy of far UV.<sup>143</sup>

## Hydrogen Peroxide Systems for Room Decontamination

Several systems that produce hydrogen peroxide (e.g., HP vapor, aerosolized dry mist HP) have been studied for their ability to decontaminate environmental surfaces and objects in hospital rooms. Hydrogen peroxide vapor (HPV) has been used increasingly for the decontamination of rooms in healthcare.<sup>144,145,146,147,148,149,150,151,152,153</sup> These investigators found that HP systems are a highly effective method for eradicating various pathogens (e.g., MRSA, *M. tuberculosis*, *Serratia*, *C. difficile* spores, *Clostridium botulinum* spores) from rooms, furniture, and equipment. Using a before-after study design, Boyce and coworkers have shown that use of HPV was associated with a significant reduction in the incidence of *C. difficile* infection on five high-incidence wards.<sup>144</sup> A recent paper by Passaretti and colleagues<sup>154</sup> demonstrated that environmental decontamination with HPV reduced the risk of a patient admitted to a room previously occupied by a colonized or infected patient with a multidrug-resistant organism (MDRO) from acquiring an MDRO by 64 percent compared to using standard disinfection methods. However, HP system decontamination was shown to require more than four times longer to complete than conventional cleaning thus resulting in prolonged bed turn-over time.<sup>155</sup>

## Comparison of UV Irradiation versus Hydrogen Peroxide for Room Decontamination

The UV-C system studied and the systems which use hydrogen peroxide have their own advantages and disadvantages (Table 31-4)<sup>124</sup> and there is now ample evidence that these "no touch" systems can reduce environmental contamination with healthcare-associated pathogens. However, each specific system should be studied and its efficacy demonstrated before being introduced into healthcare facilities. The main advantage of both units is their ability to achieve substantial reductions in vegetative bacteria. As noted previously, manual cleaning has been demonstrated to be suboptimal as many environmental

surfaces are not cleaned. Another advantage is their ability to substantially reduce *C. difficile* as low-level disinfectants (e.g., quaternary ammonium compounds) have only limited or no measurable activity against spore-forming bacteria.<sup>4</sup> Both systems are residual free and they decontaminate all exposed surfaces and equipment in the room.

The major disadvantages of both decontamination systems are the substantial capital equipment costs, the need to remove personnel and patients from the room thus limiting their use to terminal room disinfection (must prevent/minimize exposure to UV and HP), the staff time needed to transport the system to rooms to be decontaminated and monitor its use, the need to physically clean the room of dust and debris, and the sensitivity to use parameters. There are several important differences between the two systems. The UV-C system offers faster decontamination which reduces the "down" time of the room before another patient can be admitted. The HP systems have been demonstrated to be more effective in eliminating spore-forming organisms. Whether this improved sporicidal activity is clinically important is unclear as studies have demonstrated that although environmental contamination is common in the rooms of patients with *C. difficile* infection, the level of contamination is relatively low (also true for MRSA, VRE). Finally, the HP system was demonstrated to reduce *C. difficile* or MDRO incidence in clinical studies while similar studies with the UV-C system have not been published. If additional studies continue to demonstrate a benefit, then widespread adoption of these technologies should be considered for terminal room disinfection of certain patient rooms (e.g., Contact Precautions) in healthcare facilities.

**Table 31-4** Advantages and Disadvantages of Room Decontamination by Ultraviolet Irradiation and Hydrogen Peroxide<sup>1</sup>

Decontamination by Ultraviolet Irradiation	Decontamination by Hydrogen Peroxide (HP) Systems
<p>Advantages</p> <ul style="list-style-type: none"> <li>Reliable biocidal activity against a wide range of healthcare-associated pathogens</li> <li>Room surfaces and equipment decontaminated</li> <li>Room decontamination is rapid (15-25 minutes) for vegetative bacteria</li> <li>Effective against <i>Clostridium difficile</i>, although requires longer exposure (~50 minutes)</li> <li>HVAC (heating, ventilation and air conditioning) system does not need to be disabled and the room does not need to be sealed</li> <li>UV is residual free and does not give rise to health or safety concerns</li> <li>No consumable products so costs include only capital equipment and staff time</li> <li>Good distribution in the room of UV energy via an automated monitoring system</li> </ul>	<p>Advantages</p> <ul style="list-style-type: none"> <li>Reliable biocidal activity against a wide range of healthcare-associated pathogens</li> <li>Room surfaces and equipment decontaminated</li> <li>Effective against <i>Clostridium difficile</i></li> <li>Useful for disinfecting complex equipment and furniture</li> <li>Does not require that furniture and equipment be moved away from the walls</li> <li>HP is residual free and does not give rise to health or safety concerns (aeration unit converts HP into oxygen and water)</li> <li>Uniform distribution in the room via an automated dispersal system</li> <li>Demonstrated to reduce healthcare-associated infections (i.e., <i>Clostridium difficile</i>)</li> </ul>
Disadvantages	Disadvantages

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• All patients and staff must be removed from the room prior to decontamination</li> <li>• Decontamination can only be accomplished at terminal disinfection (i.e., cannot be used for daily disinfection) as room must be emptied of people</li> <li>• Capital equipment costs are substantial</li> <li>• Does not remove dust and stains which are important to patients and visitors, and hence cleaning must precede UV decontamination</li> <li>• Sensitive to use parameters (e.g., wavelength, UV dose delivered)</li> <li>• Requires that equipment and furniture be moved away from the walls</li> <li>• Studies have not been conducted to demonstrate whether use of UV room decontamination decreases the incidence of healthcare-associated infections</li> <li>• Reduced effectiveness when surfaces were not in direct line-of-sight</li> <li>• Presence of organic matter reduces the efficacy of UV</li> </ul> | <ul style="list-style-type: none"> <li>• All patients and staff must be removed from the room prior to decontamination</li> <li>• HVAC system must be disabled to prevent unwanted dilution of HP during use and the doors must be closed with gaps sealed by tape</li> <li>• Decontamination can only be accomplished as terminal disinfection (i.e., cannot be used for daily disinfection) as room must be emptied of people</li> <li>• Capital equipment costs are substantial</li> <li>• Decontamination requires ~2.5 to 5 hours</li> <li>• Does not remove dust and stains which are important to patients and visitors, and hence cleaning must precede UV decontamination</li> <li>• Sensitive to use parameters (e.g., HP concentration)</li> <li>• Presence of organic matter reduces the efficacy of HP</li> </ul> |
|--|--|

## CONTACT TIME FOR DISINFECTION OF NONCRITICAL SURFACES AND PATIENT CARE EQUIPMENT

The Centers for Disease Control and Prevention (CDC) guideline discusses a 1-minute contact time (i.e., wet time) for low-level disinfection of noncritical environmental surfaces and patient care equipment. In order to get EPA clearance of the CDC guideline it was necessary to insert the sentences "By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA."<sup>1</sup> There

are several points that should be made about this apparent disconnect between label instructions and what scientific studies demonstrate to include: (1) multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens causing healthcare-associated infections with a contact time of at least 1 minute<sup>1</sup>; (2) there are no data that demonstrate improved infection prevention

by a 10-minute contact time versus a 1-minute contact time. Further, the only way an institution can achieve a contact time of 10 minutes is to reapply the surface disinfectant multiple times to the surface (which is unlikely) as the typical dry time for a water-based disinfectant is 1.5 to 2 minutes. Lastly, as important as disinfectant contact time is to surface disinfection nothing is more important than the thoroughness of cleaning/disinfecting all hand contact surfaces (e.g., environmental surfaces or patient care equipment) as current studies demonstrate that less than 50 percent of high-risk objects are cleaned/disinfected at terminal cleaning.<sup>52,156</sup> Wiping all "hand contact" or "touchable"

surfaces/equipment, and not just perceived "high-risk" surfaces/equipment, is essential because "high-risk" surfaces/equipment have not been epidemiologically defined. In addition, "high touch" surfaces have only recently been defined but there was no significant difference in microbial contamination of "high," "medium," and "low" touch surfaces.<sup>157</sup> If an institution chooses to use a product with a

nonachievable label claim (e.g., 10 minutes), it should prepare a formal risk assessment (see <http://www.learningace.com/doc/606420/219354ffef63704bf418d26b1b8713f1/surfdisriskassess2011>) to be presented to surveyors (e.g., The Joint Commission) when challenged. Alternatively, the hospital could purchase and use for low-level disinfection of noncritical surfaces and patient care equipment an EPA-registered disinfectant with an achievable contact time such as a disinfectant with a 30 second to 2

minute bactericidal claim (see

<http://www.learningace.com/doc/606420/219354ffef63704bf418d26b1b8713f1/surfdisriskassess2011>).

Another issue is which pathogen on the disinfectant label should be used to identify contact time (e.g., bacteria, *Candida*, mycobacteria, spores) for surfaces in healthcare facilities. The CDC guideline based the 1-minute contact time on demonstration of bactericidal activity for vegetative bacteria such as *S. aureus*, *Enterococcus*, *E. coli*, coagulase-negative *Staphylococcus*, *Pseudomonas aeruginosa*, *Klebsiella* spp., *Enterobacter* spp., etc. These vegetative bacteria are the pathogens that cause the vast majority of healthcare-associated infections (HAIs) (85 to 90 percent).<sup>158-159</sup> Further, contaminated surfaces with organisms such as *Candida*, nontuberculous mycobacteria and other fungi have rarely, if ever, been shown to be a risk factor for HAIs. The only exception to this principle is the use of EPA-registered disinfectant effective against *C. difficile* spores or norovirus for disinfecting the rooms of patients with one of these pathogens (see

<http://www.learningace.com/doc/606420/219354ffef63704bf418d26b1b8713f1/surfdisriskassess2011>).

## ASSESSING RISK TO PATIENTS FROM DISINFECTION AND STERILIZATION FAILURES

Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon. A 15-step algorithm has been constructed to aid infection prevention and control professionals in the evaluation of potential disinfection and sterilization failures.<sup>13-14</sup> Patient notifications due to improper reprocessing of semicritical (e.g., endoscopes) and critical medical instruments have occurred regularly.<sup>13</sup> This article also provides a method for assessing patient risk for adverse events, especially infection. Use of an algorithm (Table 31-5) can guide an institution in managing potential disinfection and sterilization failures.

**Table 31-5** Protocol for Exposure Investigation After the Failure to Follow Disinfection and Sterilization Principles

1. Confirm disinfection or sterilization reprocessing failure
2. Immediately embargo any improperly disinfected or sterilized items
3. Do not use the questionable disinfection or sterilization unit (e.g., sterilizer) until functioning has been assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection or sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection or sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of State and Federal authorities
12. Consider patient notification
13. If patients are notified, consider whether such persons require medical evaluation for possible postexposure therapy with appropriate anti-infectives
14. Develop long-term follow-up plan to prevent similar failures in the future
15. Perform after-action report

Modified from Rutala and Weber.<sup>13</sup>

## OTHER DISINFECTION AND STERILIZATION ISSUES (SELF-DISINFECTING SURFACES, NEW TECHNOLOGIES)

Continued improvements in technologies for disinfection and sterilization may result in reduced risks from surfaces or instruments. Several promising new technologies are under examination to include self-disinfecting surfaces that are created by impregnating or coating surfaces with heavy metals (e.g., silver or copper), germicides (e.g., triclosan), or miscellaneous methods (e.g., light-activated antimicrobials).<sup>160</sup>

Similarly, development of new technologies for sterilization (e.g., ozone with hydrogen peroxide vapor) and disinfection will continue as we search for processes with improved compatibility of instruments and faster instrument turnaround.<sup>161</sup> Lastly, the intricate design of instruments, configuration of instrument trays, etc. have resulted in complicated reprocessing instructions to include extended cycle times, weight limits for instrument trays, wet packs, a variety of packaging systems, and loaned instruments for specialty operative procedures (e.g., orthopedic, spinal surgeries).<sup>162</sup>

## Conclusions

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. Cleaning should always precede high-level disinfection and sterilization. Strict adherence to current disinfection and sterilization guidelines is essential to prevent patient infections and exposures to infectious agents.

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## Reprocessing Single-Use Devices

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### Abstract

*Increasing healthcare costs, environmental concerns, and recognition of finite resources have prompted healthcare facilities to consider reprocessing devices labeled as single-use devices. At the same time, concerns over the safety of reprocessed single-use devices led the U.S. Food and Drug Administration to develop and publish regulations for this practice. Under these regulations, reprocessors, hospital-based or third party, must meet the same standards as the original manufacturer.*

### Key Concepts

- Reprocessing single-use devices can be safe and cost-effective.
- The U.S. Food and Drug Administration has established regulations for reprocessing single-use devices.
- The U.S. Centers for Medicare & Medicaid Services recommends that hospitals use a third-party reprocessor when deciding to reprocess single-use devices.
- Reprocessing single-use devices is an acceptable practice in many countries.

### Background

For several decades, hospitals and private healthcare establishments have reprocessed various single-use devices (SUDs). The practice of using SUDs was promoted as labor-saving and cost-efficient. By 1982, at least two-thirds of all sterile devices used carried a label saying "for single use only."<sup>1</sup> Concerns about healthcare costs, changes in the reimbursement system, and concerns about the environmental impact of disposing of these devices prompted healthcare facilities to evaluate the feasibility of reusing such devices. The U.S. Public Health Service approval of the practice of reusing hemodialysis filters led

the way for current activity.<sup>2</sup>Manufacturers choose whether or not to label a device "single use," and they are not required to provide evidence to support their designation.<sup>1</sup>Many manufacturers attach the single-use label to devices they previously marketed as reusable or currently market them as reusable outside the United States. At the same time, the U.S. Food and Drug Administration's (FDA) Medical Device Reporting system has documented few adverse events associated with the reuse of SUDs.<sup>3</sup>

Still, issues of quality care and patient safety led to the publication in 2000 by the FDA of a regulatory guidance document about the reuse and/or reprocessing of devices labeled as single use.<sup>4</sup>Under the FDA regulations, reprocessors (hospital-based or third party) must meet the same regulatory standards as the original manufacturer.

## Basic Principles

- An original device is defined as a new, unused SUD.
- A SUD is a device that is intended for one use on a single patient during a single procedure.
- Reprocessing a contaminated, reusable, or "single-use" device so that it can be patient-ready includes decontaminating, functional testing, repackaging, relabeling, and sterilizing the device.
- The FDA guidance document categorizes medical devices into three classes depending on the device's Code of Federal Regulations (CFR) classification (i.e., class I, class II, and class III).<sup>5</sup>Class I devices present the lowest potential risk to the patient and carry the least regulation, whereas class III devices pose the greatest potential risk and require the greatest regulation.
- The guidance document does not apply to permanently implantable pacemakers, opened-but-unused (OBU) SUDs, hemodialysis filters, and healthcare facilities that are not hospitals. The issue of OBU devices continues to be a gray area. OBU devices, defined by the FDA as those "single use disposable devices whose sterility was breached"<sup>6</sup>(i.e., the sterile package was opened but the device was not used on a patient), are not addressed in the guidance document, leaving hospitals to determine on their own how they want to address this issue.

## Reprocessing Single-Use Devices

When considering reprocessing SUDs, hospitals are faced with the decision whether to contract with a third party or formulate an in-house plan. No matter which approach is taken, the process must comply with the FDA regulations. These include the following:

1. Registration and Listing—(Section 510 of the Food, Drug, and Cosmetic Act); 21 CFR part 807
  - a. Establishments must be registered with the FDA
  - b. "Single-use" devices that an establishment reprocesses are reported on Form FDA-2892
2. Medical Device Reporting—(Section 519 (a), (b), and (c) of the Act; 21 CFR Part 803) (see <http://www.fda.gov/cdrh/mdr/>)
  - a. Adverse events must be reported
3. Medical Device Tracking—(Section 519 (e) of the Act; 21 CFR Part 821)
  - a. A tracking system is established so devices can be located promptly
4. Medical Device Corrections and Removals—(Section 519 (f) of the Act; 21 CFR Part 806)
  - a. Any device that is corrected or removed must be reported

- i. "corrected" is defined in 21 CFR Part 806.2 (e) as "repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without it being physically removed"
  - ii. "removal" is defined in 21 CFR Part 806.2 (l) as "removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection"
- 5. Quality System Regulation—(Section 520 (f) of the Act; 21 CFR Part 820)
  - a. Current good manufacturing practice requirements
    - i. Governs the methods and controls used for design, manufacturer, packaging, labeling, storage, installation, and servicing of devices, and includes all class II and class III devices and some class I devices
    - ii. Addresses corrective and preventative action requirements
    - iii. Processes validation requirements mean establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications<sup>7</sup>
- 6. Labeling—(Section 502 of the Act; 21 CFR Part 801)
  - a. General labeling requirements include
    - i. Name and place of manufacture
    - ii. Adequate directions for use
- 7. Premarket Notification and Approval Requirements—(Sections 510, 513, 515 of the Act; 21 CFR Parts 807 and 814)
  - a. Level of premarket submission is based on the FDA classification of the device
  - b. Two types of submissions
    - i. Premarket notification—510K is required for class I and class II devices unless the device is specifically exempted
    - ii. Premarket approval (PMA) application is required for all class III devices depending upon the type of device. A premarket notification (510K) may also be required.

Healthcare facilities considering contracting with a commercial third-party reprocessor have the responsibility of knowing that reprocessing an SUD presents no greater risk to their patients' health and safety.<sup>6</sup>The decision to contract with a reprocessing company should be based on a thorough review and FDA approval of their 510(k) application.<sup>8</sup>An on-site visit should be scheduled, with the opportunity to meet with personnel involved in the process, and a review of the company's policies. The visit should also include an opportunity to observe the cleaning and decontamination, inspection and testing, and sterilization load preparation process, as well as reviewing quality control records.

In light of the regulations previously outlined, it is unlikely that hospitals will choose to maintain in-house reprocessing programs because of the cost of developing and maintaining programs that meet all of the FDA requirements. The Centers for Medicare & Medicaid Services (CMS) encourages hospitals that decide to reprocess SUDs to use third-party reproducers rather than establishing in-house programs. Facilities that consider engaging the services of a third-party reprocessor should clearly define their goals and objectives for a successful alliance. Administrative understanding and support for the program are essential if the facility is to maximize opportunities and realize the financial benefits of reprocessing. Information about specific third-party reproducers, including inspection histories, is available from the FDA freedom of information staff on the agency Website (<http://www.fda.gov/cdrh>).

In June 2004, the FDA revised its procedures and time frames for reviewing the validation data submitted to the FDA for certain reprocessed SUDs.<sup>9</sup>This document, currently in effect, supersedes the

document issued in 2003 that outlines the types of validation data the FDA recommends be submitted on cleaning, sterilization, and functional performance of certain reprocessed SUDs to ensure that they are substantially equivalent to the original products. The document provides guidance on how the FDA follows these validation data requirements, which were enacted by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

The 2004 document makes clear that after review of the validation data, the FDA issues either a letter finding the reprocessed SUD to be "substantially equivalent" (SE) to the original device or a letter requesting additional information. The manufacturer who receives the request for additional information has 30 days to respond after which the FDA makes a final decision on substantial equivalence within 60 days.

If the agency review of the validation data determines that the reprocessed SUD is "not substantially equivalent" (NSE) to the predicate device, it issues an NSE letter. Therefore, the device may no longer be legally marketed. The manufacturer may submit a new premarket notification with the validation data required by MDUFMA.

The MDUFMA requirements apply to critical reprocessed SUDs, which contact normally sterile tissue or body space, and to semicritical SUDs, which contact intact mucous membranes without penetrating normally sterile areas of the body.

The revised guidance is posted on the FDA's Website at <http://www.fda.gov/cdrh>.

## Conclusions

Reprocessing SUDs is safe and cost-effective, and the FDA has established regulations for reprocessing SUDs. Given the cost of developing and maintaining a program that meets FDA regulations governing the reprocessing of such devices, most hospitals use a third-party reprocessor.<sup>10</sup>

## Future Trends

Hospitals have been forthcoming about the pressures they face in today's healthcare climate, including the need to balance costs with safety and sustainability.<sup>11</sup> Recycling, as much as possible including reprocessed single-use medical devices, has become a method of controlling costs while showing patients and their families that hospitals are as concerned about their impact on the environment as they are about saving lives.

According to data reported by the Millennium Research Group, the U.S. market for reprocessed medical devices is expected to show strong growth through 2017 fueled by economic and environmental concerns of U.S. healthcare facilities.<sup>12</sup>

A Government Accountability Office report from 2008 found that, based on available information, including well-developed clinical studies, reprocessed SUDs do not present a greater risk to patients than the use of new devices. Furthermore, third-party reprocessors are actually reducing costs associated with medical devices and reducing medical waste without compromising patient safety.<sup>3</sup> Faced with 21st century challenges, the future appears solid for companies involved in reprocessing SUDs.



## International Perspective

The reprocessing of SUDs is a commonplace practice worldwide. While the practice is a regulated issue in the United States, the available evidence indicates that reprocessing SUDs in most other nations, both developed and developing, is unregulated. In many instances, especially in Asia and Africa, unregulated and uncontrolled reuse of these devices is common if not the norm.<sup>13</sup> The lack of guidelines

or regulations creates great disparity in practice. The economic factors that affect the availability of medical care and devices in developing countries often create situations in which the only possibility of having the supplies needed necessitates reprocessing SUDs.<sup>14</sup> Healthcare providers must evaluate the

cost of human resources needed to clean and sterilize devices to ensure that the tradeoff does not create disparity and that a balance of benefits, risks, and costs are aligned for safe patient care within their setting. Even in neighboring countries such as Canada, reprocessing of SUDs is not uniformly regulated or practiced in all provinces.<sup>15</sup> Therefore, the international infection prevention and control

community has an opportunity to pool knowledge and practice information to develop guidelines to assist in the development and implementation of safer and consistent reprocessing of SUDs. The following Website provides a 2011 update on reprocessing SUDs in Canada:

**<http://www.cadth.ca/products/environmental-scanning/environmental-scans/environmental-scan-28>**

## Supplemental Resources

Canadian Agency for Drugs and Technologies in Health. Available at: **<http://www.cadth.ca>**.

MEDEC. Policies in Canada for reprocessing single-use medical devices. Available at: **[www.medec.org/node878](http://www.medec.org/node878)**.

U.S. Food and Drug Administration's Center for Devices and Radiological Health. Available at: **<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm>**.

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